EXHIBIT W

IN RE: PELVIC MESH LITIGATION		PHILADELPHIA COUNTY
----------X		COURT OF COMMON PLEAS
Sharon Carlino and	:	TRIAL DIVISION - CIVIL
Charles Carlino,	:	
Plaintiffs,	:	JUNE TERM 2013
V.	:	
Ethicon, Inc., et al.,	:	No. 3470
Defendants.	:	
----------X		

Toronto, Ontario, Canada

Thursday, November 5, 2015

Deposition of VLADIMIR IAKOVLEV, M.D., a witness herein, called for examination by counsel for the Defense, in the above-mentioned matter, the witness having been duly sworn, taken at the Shangri-La Hotel, 188 University Avenue, Toronto, Ontario, Canada commencing at 9:20 a.m. on November 5, 2015, and the proceedings taken by JUDITH M. CAPUTO, RPR, CSR, CRR.

APPEARANCES:

On Behalf of the Plaintiff:
CHRISTOPHER J. ZIMMERMAN, Esquire
Anderson Law Offices, LLC
1360 West 9th Street, Suite 215
Cleveland, Ohio 44113
216.456.8870
christopher@andersonlawoffices.net

MICHAEL A. TRUNK, Esquire
Kline & Specter, P.C.
1525 Locust Street
Philadelphia, Pennsylvania 19102
215.772.1374
michael.trunk@klinespecter.com

On Behalf of the Defendants:
PHILIP J. COMBS, Esquire
Thomas, Combs & Spann, PLLC
300 Summers Street, Suite 1380
Charleston, West Virginia 25301
304.414.1805
pcombs@tcspllc.com

APPEARANCES:

On Behalf of the Defendants (cont'd):

M. ANDREW SNOWDEN, Esquire
Butler Snow, LLP
The Pinnacle at Symphony Place
150 3rd Avenue South, Suite 1600
Nashville, Tennessee 37201
615.651.6700
andy.snowden@butlersnow.com

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-- Upon commencing at 9:20 a.m.

EXHIBIT NO. 1: Amended Notice of Deposition of Vladimir Iakovlev, M.D.
EXHIBIT NO. 2: Flash Drive Containing Reliance Documents.

VLADIMIR IAKOVLEV,
having been duly affirmed, testified on his oath as follows:

DIRECT EXAMINATION BY MR. COMBS:

Q. Dr. Iakovlev, my name is Thomas Combs. I am here to take your deposition today in the Carlino case. It's my understanding you brought your reliance materials?

A. Yes, I brought case-specific reliance materials.

Q. Okay. And that's on the thumb drive that we've marked as Exhibit 2?

A. Yes.

Q. All right. And who retained you in this case?

A. My first contact was with Anderson Law.

Q. And when did that occur?

A. Sometime earlier this year.

Q. Sometime in 2015?

A. Yes.

Q. Will there be anything on the thumb drive that will tell us when that occurred?

A. There will be chain of custody; it will show when I received the specimen.

Q. And right before the deposition started, Mr. Zimmerman told me that you haven't billed anything in the Carlino case; is that right?

A. No.

Q. So would you be able to estimate for us how much time you spent on the Carlino case?

A. Roughly, one expert report takes about 20 hours, average.

Q. So something in the neighborhood of 20 hours?

A. Yes.

Q. I understand it could be more, it could be less, but in that ballpark?

A. Yup.

Q. Your role in this case is solely as an expert witness; is that correct?

A. Yes.

Q. Okay. I mean, for example, you have played no role in providing treatment to Ms. Carlino?

A. No.

Q. And do you know who her current treating physicians are?

A. Current, or who was in the records? I mean, the only information I had about her treatment care was what was in the records.

Q. Okay. And when you say "in the records", what records?

A. They are provided in the folder. There is specific folder, medical records I received, I reviewed.

Q. Okay. And on the reliance list, the only medical records are Item 601 which says, "Jersey Shore University Medical Center"?

A. It's an umbrella term. But if you want to know exactly what medical records are reviewed, you would go to that folder and see. I review all records I receive in terms of that.

Q. So if there are other records on a thumb drive, those would be records that are not on the reliance list?

A. Well, again, see, if you have records at one institution, they can go from one time point to another. So I might have received only one portion. Or I received extra records which are going under the umbrella.

So as I said, I mean, this would be a general description. But if you want to know exactly what medical records I could review, and I reviewed, I would need to go to the folder.

Q. Okay. As we sit here right now, do you remember what you reviewed?

A. No. It's not a memory test, I can check.

Q. No, it's not a memory test. But you know, I mean, all I have was your report and it has "Item 601, Jersey Shore University Medical Center Records". And so I'm asking you about what the records are that you reviewed.

So whatever records you had in this case were on the thumb drive?

A. Yes.

Q. Is the report that you provided us dated August 28th, 2015, is that your complete opinion in this case?

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A. Yes. At that date, I completed the report. So I didn't receive anything additional to supplement or extend.
Q. Thank you. Maybe I didn't ask the question very well. But that's what I wanted to make sure. That, basically, this is the final report in this case; there is no supplemental report?
A. Yes. At this stage, yes.
Q. And so are all of the opinions that you plan to offer at the Carlino trial, contained within this report?
A. Unless I receive new material.
Q. And at this time, you're not aware of any new material that you would be receiving?
A. Not yet.
Q. Dr. Iakovlev, I want to put something on the record, because I didn't understand it.
I thought that this thumb drive that you gave us was just your reliance materials for the Carlino case; and that's not correct, is it?
A. No. That's for the whole date.
Q. Okay, thank you. Let me just put

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it on the record, so it's clear.
MR. COMBS: The thumb drive that Dr. Iakovlev provided to us that we've marked as Carlino Exhibit 2, we're also going to mark as Ramirez Exhibit 2, and I didn't understand that until it was pulled up.
BY MR. COMBS:
Q. Okay. And, obviously, I'll be asking you about the Ramirez materials in a different deposition that is going to occur.
So the record is clear, everything that you had that you're relying on in both the Carlino and the Ramirez case, that you brought to the case-specific deposition is contained in this thumb drive?
A. That is correct.
Q. Okay, thank you.
Dr. Iakovlev, attached to the report that you provided on August 28, 2015, was a copy of your CV. And I see that on the thumb drive there is a different CV dated November 3rd, 2015.
Would you be able to summarize for me what the changes are to the CV?
A. Mostly publications.

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Publications, presentations.
Q. Any change in your employment status?
A. No.
Q. You're at St. Michael's, right?
A. Yes.
Q. And what is your position?
A. Director of cytopathology and pathologist.
Q. All right. And you're also at -- are you an assistant professor at the University of Toronto?
A. Yes, I am.
Q. And when did you become an assistant professor?
A. About five years ago. Five or less, I don't remember now.
Q. All right. The CV says 2008 to present; is that roughly correct?
A. Probably.
Q. Okay. Dr. Iakovlev, I'm looking at the directory from the thumb drive that you brought, and it's got three groups of materials. It's got your chain of custody form; it's got a group of medical records; and then it has a CV on

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it.
A. No. The thumb drive contains two folders, case-specific information for Carlino, for Ramirez. And then separately there is CV, because CV is common for both.
And when you open separate folders, there will be case-specific information what I have for that specific case.
Q. And again, I just didn't ask that very well.
We've got the folders out, and so we've got -- we've got the chain of custody form, we've got the grouping of medical records, and then we've got the CV.
And is that the total of the case-specific informations for Carlino?
A. It is a weird way of --
Q. It looks different on a PC.
A. -- it's not Explorer.
So how it's grouped, there are two folders, and CV is separate.
Q. Sure. But let's go back to the Carlino folder.
A. When we go back to each case

specific, there will be a folder for medical records. And there will be separate files for chain of custody forms and billing, if I have billing.

Q. Okay. Thank you.

That's what I was trying to establish. In the case-specific materials in the Carlino case include the chain of custody form and the medical records?

A. That's correct.

Q. Not anything else?

A. That's correct.

Q. Are there any notes that you made regarding work that you did on the Carlino case that are not contained in the report or the thumb drive that you brought today?

A. I don't make any hand notes.

Q. So during the examination that you did of this specimen or the slides, there would be no notes reflecting that?

A. There is a pathology report. Sorry, I didn't include it. I can provide it to you later on, or it might be already in the folders.

Q. Okay. So in addition to the two things on the thumb drive, the third group of materials that you would have for case-specific for Carlino, would be a pathology report that you prepared?

A. That's correct.

Q. Okay. Anything else?

A. No.

MR. COMBS: Do you have the St. Michael's pathology report?

MR. ZIMMERMAN: No.

BY MR. COMBS:

Q. Oh, okay.

A. This is more of hand notes, whatever you call it, but it's not hand note.

Q. Is that what you're referring to?

A. Yes.

Q. All right. We do have it. So it's an exhibit to your report.

I was not understanding exactly what were you referring to, but thank you. So we do have that.

Anything else? Any other Carlino case-specific materials?

A. No.

Q. Do you have any photographs that are not contained in the report?

A. No.

Q. Are there slides that you prepared that you did not photograph for the report?

A. I take photographs from specific areas, most representative. But I think in this case I sent all slides to you. There's a chain of custody form which describes what I send back.

Q. So would there be slides that are not photographed and contained within your report?

A. How do you mean? Photographs in the report are already there. So some additional slides which I kept at St. Michael's Hospital and didn't send to you? I don't understand the question.

Q. All right. In your report you have photographs that are identified SC-1 through SC-18?

A. Yes.

Q. Now my question is: Do you have photographs of all of the slides contained within SC-1 through SC-18?

A. No, these are all the photographs I have. I prepared these photographs.

Q. Okay. So some of the slides that you reviewed for Ms. Carlino's specimen, are not photographed and --

A. Could, could have not. I don't remember now.

Probably I took at least one image from each slide. But again, I don't remember now.

Q. As we sit here today, you don't remember whether you have a photograph from each of the Carlino slides?

A. No, I don't remember. I take only photographs to demonstrate features.

Q. And what does that mean? What does it mean that you take photographs only to demonstrate features?

A. It means that I use photographs to demonstrate pathological findings. It's not a documentation, it's illustration.

Q. What does that mean?

A. Illustrate pathological findings. When I do assessment, I assess slides in the microscope with my eyes. And then when I prepare

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the report, then I take photographs just specifically for that report.

Normal pathology, we don't take photographs. We just provide assessment using microscope.

Q. And when you say "normal pathology", do you mean, for example, the pathology that you would do at St. Michael's?

A. Yes. So when I was preparing the surgical pathology report, which you have, I wasn't taking any photographs. I was just looking at the specimen, in the microscope, and generating report normally, as I would normally do for any sample.

But because I was asked to also prepare an expert report, so I needed to provide a larger sort of document with illustrations. That's why I took photographs.

Q. So when you're doing your work at St. Michael's, you would have a pathology report that would be one, or maybe one or two pages long, and that would contain your findings for that case; is that correct?

A. That's correct.

Q. And when you're doing the expert

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report, you would have things in addition to the materials that you would have when you're preparing a pathological report at St. Michael's?

A. It's not additional material; it would be additional description. Description is much longer with illustrations.

Q. When you were talking about the photographs that you have in your report, what's the criteria that you use to decide to make a photograph of a particular slide?

A. When I make assessment, I see a specific pathological feature, and then I find an area which is most representative of that feature, and I take a photograph to demonstrate it for a non-pathologist.

Q. And you say that there's a photograph taken that is most representative of that feature; what does that mean?

A. Not just most representative, sometimes it's easy to explain using it.

So it may not be most representative for a pathologist, but it would be most useful for a non-pathologist. So there are different criteria. But I use it more, as I said, as an

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illustration to explain, to show the feature to a non-pathologist. Because this expert report is aimed at non-pathologists.

Q. So for example, SC- 1 and SC-2, you call out that you're describing the scar bridging, fibrous scar bridging.

Would those two photographs be the best example that you found in the Carlino pathology of scar bridging?

A. Not necessarily best example. There might be different areas. I mean, the whole thing might be good example.

Sometime you just take first available area; it depends on the feature. And some features are focal, some features are diffused.

Q. I couldn't hear you.

A. Some features are focal; some features are diffused.

Something like bridges, bridging fibrosis is diffused. I can take picture of any part of the mesh and can demonstrate it.

But for something like nerve ingrowth or neural ganglia, or something else, it would be focal. So I would have to search for it, it

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depends on the feature.

Q. And so, for example, the two photographs that you selected for fibrous scar bridging, those would be -- did you pick those two slides to depict that feature?

A. Yes.

Q. All right. And for SC-4 and 5, where you're discussing foreign body reaction, you picked those two slides to discuss foreign body reaction?

A. With foreign body, I mean, if you flip to the initial -- one more page. The very first photograph.

You see it was foreign body, pretty much I can take picture of any of those fibers and there will be foreign bodies. I don't have to choose.

Sometimes I do have to, because of the artifacts, some sections don't come out flat. So I have to pick, for technical reasons, rather than for pathological reasons. So it's a combination of factors. Because picture need to be sort of visually understandable for a non-pathologist, as I said, if there are too many artifacts or something

else.
Q. In the photographs you have in your report where you go through scar bridging, foreign body reaction, are those photographs the best examples that you had of that phenomena?
MR. ZIMMERMAN: Objection, asked and answered.
THE WITNESS: Not necessarily best examples. As I said, I mean, sometimes they are just showing well enough for a non-pathologist. I am more concerned explaining things rather than finding the best example.
BY MR. COMBS:
Q. Is there any criteria that you can point to about why you selected these slides to photograph?
A. Just to show us what feature I observed. As I said, with bridging fibrosis, I can take pictures of any part of the mesh.
If we go back to the pathology report it will give you percentage of pores which are bridged. In this case, it is 100 percent.
So any part of the mesh would show bridging fibers. So there was no selection; I

probably just took the first available few.
Q. So these would just be the first two available slides that you looked at?
A. Yeah.
Q. For the slide three, where you say "the curled portion", why did you pick that slide?
A. That's a specific feature, it was a focal. You get some areas which are flat, some areas which are twisted or deformed somehow.
So then I would have to look for it. And if it's there, then I take picture of it. It's a focal feature.
Q. If there were any other areas of curled portion of the mesh, would you have taken a picture of that as well?
A. No. We cannot squeeze 50 photographs in one report. I would just take the most representative, or the most illustrative for a non-pathologist.
Q. Okay. And what's the criteria that you use in deciding what's the most illustrative? Is it just what you like the best?
A. Pretty much. I look at it, and think: Would the non-pathologist understand it?

That's how I pick them.
Q. And --
A. Images are just illustrations, as I said. I mean, I'm not taking them as documentation or evidence.
Q. I couldn't hear you.
A. I'm not taking images as documentation or evidence. I'm taking them to illustrate the features.
Q. For your notice of deposition, we have Schedule A. And the Schedule A has 30 categories of documents.
Is everything that you had in your possession that is responsive to the Schedule A contained on the thumb drive?
A. Case-specific.
Q. Yes.
A. There wasn't anything of my general opinions.
Q. Okay. So anything you had that is case-specific for Ms. Carlino is included on the thumb drive that we've marked as Carlino Exhibit 2?
A. Either it was provided to you before, or is included on the thumb drive. Like

report was provided to you, so I didn't copy it on the thumb drive.
Q. Okay. So we've got the report, we've got the materials on the thumb drive; we've got the pathology that got left off the thumb drive; anything else?
A. No.
Q. Okay. So, if there is any -- if we went through -- Dr. Iakovlev, all I'm trying to do is not go through 30 of these categories.
So if you had anything responsive to any of the 30 categories, it's either -- it's the report, or it's the materials on the thumb drive Exhibit 2 for a case-specific report.
A. Yes, for the case-specific reports, everything I had is either in the documents you were provided before, as pathology report and expert report, or on the thumb drive; there is nothing else.
Q. Okay. Thank you.
A. Or you received the slides. That's another category of items.
Q. Okay. Dr. Iakovlev, we last took your deposition on September 11, 2015. My partner

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David Thomas took it in the Mullins case.

Have you published any literature since September 11, 2015?

A. There were two abstracts published in Canadian Journal of Surgery; they are in my CV.

Q. So the journal, the abstracts were published in, was Canadian Journal of Surgery?

A. Yes.

Q. They're listed on your CV?

A. Yes, they are.

Q. Can you just very briefly tell us what those publications involved.

A. One was similar to the degradation paper. I had to submit an abstract to present it at the meetings, so it was just an outline of the degradation paper.

And the second one was describing migration of the mesh for hernia applications. The meeting was all for general surgeons and it was -- both were presented at the Canadian Hernia Society section of the meeting.

Q. Has that occurred yet?

A. Yes.

Q. When did that occur?

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A. In September.

I also presented at the Bard de Vols (ph) Annual Conference in Berlin, they invited me to give a talk. But that presentation didn't have an abstract, it was an invited lecture.

Q. Is that at Bardebolton (ph)?

A. Bard de Vols.

Q. Have you conducted any new scientific testing since September 11, 2015?

A. You mean research testing?

Q. Yes.

A. I mean, I have ongoing projects.

Q. Okay. Anything new since your deposition was taken in September 11, 2015?

A. No, nothing is finalized.

Q. Okay.

A. In terms of no new conclusions or no new results.

Q. Okay. Thank you. I just want to make sure that I can rely on any testing that you're going to testify about in the Carlino case. I just want to make sure that we have had the opportunity to depose you on that.

So no new conclusions or results from any testing since your deposition in September of 2015?

A. That's correct.

Q. When I looked through your reliance list, the only deposition that I saw was Dr. Barbolt's deposition from Ethicon. Am I correct that you have no depositions that are related to case-specific issues in the Carlino case?

A. That is correct. I almost never review deposition records, rarely, when I have really specific question.

Q. And for the Carlino case, there were no depositions that you reviewed?

A. That's correct.

Q. I realize that they're on the flash drive, but since we don't have a hardcopy of the flash drive, I just want to make sure that I understand. Would all of the records that you reviewed in the Carlino case be on that flash drive?

A. You mean medical records?

Q. Yes, sir. Case-specific medical records?

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A. That is correct.

Q. So whatever you reviewed, it's the folder that says "medical records" on the Carlino matter?

A. That is correct.

Q. Since your deposition in September of 2015, have you changed your methodology in any way regarding the collecting of samples or staining of slides?

A. No. It's standard diagnostic protocol of an accredited lab and I don't change it.

(Reporter sought clarification).

A. It's a standard protocol for diagnostic, accredited diagnostic lab.

Q. When you say "accredited lab", is that a CLIA certified lab?

A. We have several certifications because, I mean, there is an overlap between the U.S. and Canadian systems.

And primarily, we need to respond to a Canadian certification. I think it is, but I'm not sure, I don't remember now.

One day I think I brought it for the

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deposition, all of the certifications and clearance, but now I don't remember.

We are for sure certified by the Ontario QNPLS.

Q. Sorry, the Ontario --

A. QNPLS and ISO, that's for sure. Because we just have it like a week ago. But the rest of the accreditations, I don't remember.

Q. Was the lab previously certified by ISO?

A. Of course.

Q. Dr. Iakovlev, have you had any communications with other expert witnesses in the Carlino case?

A. No.

Q. About Carlino?

A. No.

Q. So no conversations with any of the plaintiffs' other expert witnesses?

A. No.

Q. Any material from those witnesses that you're relying on?

A. No, just medical records. If you think about material, that can be classified as

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material.

Q. Okay. And what I'm talking about are expert reports, expert opinions, or expert depositions from the plaintiffs' experts in Carlino.

Have you relied for any aspect of your testimony, on any other expert witnesses?

A. No, I didn't receive anything, I didn't ask for anything.

Q. Have you reviewed any materials from the defense expert witnesses in Carlino?

A. No.

Q. Dr. Iakovlev, I wanted to ask you some questions about your process for the clinicopathological correlation that you have set forth at page 86 of your report.

And in it you've got three criteria. The first:

"Clinical records were screened for events and symptoms with temporal relationships to meet placement alteration or excision." [as read]

And then you have two more bullet

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points, I won't read them. But I wanted to ask you about those three. Where did those criteria come from?

A. That's how I approach them. I just put it in bullet format. That's usually what we do as pathologists, because when you receive a specimen, we try to understand what's going on, and interpret the findings in view of the clinical information.

Sometimes it's straightforward, there is not much to explore; and sometimes it's complicated, so you have to go further back 15, 20 years to figure out what was happening at that time. But that's a general approach for pathologists when they work-up their cases.

Q. Can you refer me to any published source that sets forth this criteria?

A. No. This was formulated specifically for non-pathologists, just to explain how pathologists function. I mean, it's not a formal sort of protocol for pathologists.

Q. All right. And I misunderstood what you were explaining to me.

This criteria that you set forth on

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page 86 of the Carlino report, that's a criteria that you used, that you've used -- strike that.

The criteria that you set forth on page 86 of the Carlino report, that's the criteria you've used when making your clinicopathological correlation for expert reports?

A. Yes and no. As I said, the criteria, or the way pathologists function is independent for medical-legal work. We review histories, we try to understand what's going on and we interpret our findings in view of the history, and views, and knowledge.

But to make it more understandable for non-pathologists who would be reading the expert report, I put it in the bullet format.

Q. Okay. And is there any published source that you can refer me to, that would say, these are the criteria for clinicopathological correlation?

A. How would it be a published source because it's done just specifically to explain to non-pathologists who would be reading expert report.

It's not, it's not -- this bullet

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format points is not formulated for pathologists. It's formulated to explain the readers of this expert report how pathologists would be functioning.

Q. Is the answer to the question, no, there's no published source that would set forth these criteria?

A. No, I don't think there would be.

Well, I mean, I don't know much about publications for medical-legal work for pathologists. It is unique field.

Q. You're not aware of any published source that would support the criteria that you set forth on page 86 of your report?

A. No, because I did it. I provided that bullet format.

Q. And this will be a different criteria than you would use when reviewing a case at St. Michael's, wouldn't it?

A. No, it's not a different criteria. You're mixing apples and oranges.

I did it specifically for non-pathologists to understand how pathologists function. How pathologists function is a different -- not

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different, but I mean, it's the same process, but this comes with understanding of the medicine and pathology, so during our training. So I think we're mixing things which are not -- we're trying to separate things which are inseparable.

Q. When you review a pathological specimen for your work at St. Michael's, do you review all of the clinical records of the patient?

A. No. As I said, sometimes it's straightforward. There is one question, one specific question from a clinician on specific site. I need to know what site, I need to know what's the clinical question.

Some procedures have predetermined pathological questions, so it's not being repeated. Like, if I do Pap smears, like I do 2 or 3 thousand Pap smears a year, they don't ask the same question 2,000 times, so it's predetermined.

But for some more complex cases, there will be a paragraph written on the requisition by the clinician. And if I don't have enough information, I go to clinical records.

For some specimens, I always go to medical records. And for some specimens I have to

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call up the clinician and ask. It all depends on the scenario and the complexity.

And the main purpose of this is for me to obtain enough clinical information to interpret correctly pathological findings.

So that's why I'm telling you that when I put it in bullet format, that was specifically done for non-pathologists. Because for pathologists, the entire process of training through medical school and pathology prepares us to extract needed information in a specific case.

We use our judgment based on our training, knowledge and experience. There is no -- there wouldn't be a bullet format, there are books and training, years of training, to come to this understanding.

So I just summarized it, again, based on my knowledge, experience and training, for non-pathologists.

Q. In the first criterion you reference:

"Clinical records screen for events and symptoms with temporal relationship to mesh placement,

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alterations or excision".

What is mesh alteration?

A. Cutting or transecting. Something which is not -- cannot be classified as an excision.

Q. So you would view clipping of mesh as different from excising mesh?

A. See, again, clipping, what's clipping? Sometimes they say "clip"; they just make a small cut, or transect.

Or sometimes they do clipping, they clip small fibers and then they don't submit it to pathology. Again, this is a very vague, ambiguous terminology that clinicians use.

But if there's no specimen, probably the correct term would be "transection" or "alteration" in this case.

Q. You say in here "temporal relationship"; What is the temporal relationship that you're referring to?

A. So if the symptoms occur, and they changed with timing, which allows or brings mesh into the differential diagnosis. Because if symptoms occurred before the mesh was placed, that

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would be impossible.
Or if a symptom occurred at the specific time after the mesh was placed, or altered, that gives you greater degree of certainty that the mesh is doing something.
Q. So the temporal relationship that you're referring to, did that have a defined component? Is there a specific amount of time?
A. No. It depends on the feature. It depends on my judgment. If I know mechanism, a pathophysiological mechanism which would connect it within that specific timeframe, again, knowing pathobiology, pathophysiology.
Q. Is there any written source that you could point us to regarding what that temporal relationship would be?
A. I think we're going back. This is a summary, just to put in a bullet format. This is essentially summary which pathologists gain through, like, 12 years of university training.
Q. Okay. My question is, is there any written source you could refer me to that could explain what you're using as the temporal relationship in Criteria 1 --

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A. It's my judgment. If I see, assuming -- if we're talking about scar contraction, I cannot time it to immediate postoperative period.
If there is tension in the mesh within first week after surgery, I cannot attribute it to scar contraction; that's a temporal relationship. Because scar contraction starts later, that's an example.
Q. So no written source that you can provide us?
A. No, this is not correct. Written sources are understanding of pathophysiology and pathology. So temporal relationship is determined by pathologist, or by clinician.
Q. Okay. I just --
A. I just don't understand why would you expect for each feature to be published as a temporal relationship, assuming if someone is performing the surgery?
We know that scarring occurs at specific time point, or there could be postoperative infection at specific time points. These are all temporal relationships based on the

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understanding of pathobiology.
Q. Here is my question. If there is any written source that you're relying on for Criteria 1 in the Carlino report, just tell me what it is.
A. For each specific feature, there would be a written source. Like I said, I gave you an example for scar contraction. There are papers which show when the scar contraction occurs and so forth.
So you would have to go out for each specific feature and then find the source, published source for temporal relationship.
Q. Okay. So for scar contraction, what would that temporal period be?
A. There are several papers.
First of all, there will be papers on healing, wound healing, skin wound healing. Those papers are quite old, so you probably be better going to basic pathology books like Robins.
And then specifically for mesh scar contraction, there are several papers which measured it and timed it.
Q. What are those papers?

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A. I don't remember the authors right now. They're in my reliance list somewhere.
Q. If you reviewed the reliance list, would you be able to tell me what papers you're --
A. That would be hard. It's a long list, I would probably pick it out, but it may take long time.
Q. So for mesh contraction, can you tell me what papers you rely on to set your temporal relationship?
A. I would have to go to my review papers and see what I reference in my review papers and then it will be easier this way.
Because, I mean, I cannot remember possibly all authors. There are, like, 400 or 500 papers I have read since I started my research in this.
Q. What is the --
A. -- there are some key papers which I remember, but --
Q. What are the key papers?
A. Mostly from Kosterhaliften and Klinge and my own.
Q. I couldn't hear you.

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A. Kosterhaliften and Klinge and my own, because these are focused on pathological changes.

Q. What are the temporal periods regarding mesh contraction that you rely on?

A. So when early granulation tissue fills the spaces, it cannot contract yet. The first myofibroblasts appear sometime around week five.

So starting from week five, depending on tissue healing, there will be several stages for scar contraction. Myofibroblasts can contract, reduction of extra cellular fluid will contract the tissue. And a remodeling of scar tissue, reconfiguration also contracts. So there will be a more rapid contraction within three months postoperative. Again, it's variable between people. And then there will be slower phase later on.

Q. Okay. Let me make sure that I understand that. Around week five is the beginning of scar contraction. You then have rapid contraction at three months; and then after that you have additional contraction? Is that your --

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A. Mostly. Mostly it will occur in most people around three months. But it is very variable. And then depending on repetition, because if the injury repeats, the cycle sets again.

So the scar, new scar will be put down and then contraction will continue on. So it will be slower.

So in most people, in most scenarios, the largest part of the contraction will occur around three months. Again, it's very variable.

Q. And what's the source that you rely on that most people will have scar contraction in three months?

A. In mesh? There was a paper, They actually measured it. They showed perfectly when it peaks at three months.

Q. Okay. And what is that paper?

A. Again, I'd have to search it, You'd have to give me the time.

No, we'd have to search for the paper itself. I'd have to see the paper itself, not just a heading.

Q. Okay. Well, let's go ahead and

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mark this as Exhibit 3.

EXHIBIT NO. 3: Expert Report of Dr. Vladimir Iakovlev.

THE WITNESS: So on the record, if you want me, I can do it after the deposition. I would have to open the papers, because they're in specific folders, they're in my office. Then I will find the paper where it showed the peak.

BY MR. COMBS:

Q. Okay. So after the deposition, would you just tell Mr. Zimmerman what paper you were relying on for the three-month peak?

A. Yes, I will.

Q. Okay, thank you.

And do you remember, is that a pelvic mesh paper or a hernia mesh paper?

A. I don't remember now exactly what it was.

It doesn't matter. The mechanisms behind it are not related to anatomical site; they are related to general healing mechanisms in the body.

Q. And does the paper that you're thinking about refer to contraction of mesh

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implanted for stress urinary incontinence?

A. I think we are going into general opinions now, not case-specific.

Q. Okay. What's the answer?

A. As I said, mesh contraction is not specific for anatomical site; it is driven --

Q. I just couldn't hear you -- you started talking quickly, I'm sorry.

A. Mesh contraction is not specific for an anatomical site. It's driven by general mechanisms of wound and tissue healing in the body.

So if you want to separate it, it will be an artificial separation. But I think we are moving into general opinions. We are moving away from case-specific questions.

Q. Okay. And so is the paper that you're relying on, for the temporal relationship for pelvic mesh that you're talking about in Criteria 1 in your clinicopathological correlation, is that a paper that relates to stress urinary incontinence mesh?

A. So, again, I think we're dissecting it in the wrong angle. Each specific feature, you will have timing based on pathobiology

and pathophysiology.

So we would have to go to each specific feature and then you would have to ask me for, for paper, published paper, for that specific feature. And then we would have to go through the same exercise again, and again, for each specific feature. But I think we are moving into general opinions.

Q. Well, I just want to know for this Criteria 1 here:

"Clinical records were screened for events and symptoms with temporal relationship to mesh placement, alteration or excision."

And I've asked you about contraction.

A. Yes.

Q. And so for mesh contraction --

A. As an example, we discussed mesh contraction, and I think we can stop there. Because, I mean, then we would have to go through each pathological feature and find the paper which was publishing the timing of that pathological feature.

Q. We might do that. But here's my

only question that is on the table right now is: Is the paper that you're relying on that mesh contraction occurs at three months --

A. It's not one paper. I said that paper was showing it in meshes. But there are several papers, and several papers showing scar contraction outside of mesh.

So I was relying on my understanding of the process based on several papers. It's not just one single paper.

Q. Okay, thank you.

And do any of those papers involve mesh placed for stress urinary incontinence?

A. Again, I think we're crossing sort of into general opinions, but I can answer.

Specifically for transvaginal meshes, there is more information on contraction based on clinical studies rather than pathological studies.

So I was relying on clinical descriptions of mesh contraction, when urinary obstruction occurred at a specific time point.

Q. Here is my question.

A. So the question --

Q. Do any of those studies you're

relying on deal with stress urinary incontinence mesh?

A. Yes. As I said, this would be clinical, not pathological, but clinical. Clinical papers describing as urinary obstruction -- as a complication of mesh contraction. And those papers are quite numerous.

Q. All right. In terms of pathological findings, are there any path -- strike that.

Are there any papers that are discussing the pathology of stress urinary incontinence meshes that you would rely on to say that mesh contraction occurs at three months?

A. I would have to review papers now, how much of contraction they were describing. I don't just use one paper, I read many papers and then I make summary in my head to understand the process. So I'm not plucking one paper.

Q. Okay. And I'm only asking you about stress urinary incontinence. And as we sit here today, can you refer me to any paper that discusses pathological findings showing the temporal point at which you say contraction occurred regarding the stress urinary incontinence

mesh?

A. So since this is quite artificial separation for me, I would have to review papers again, and if we agree, I can do it after the deposition.

But this would be an artificial separation. Because I do not separate meshes specifically for stress urinary incontinence. And some papers they have information which is applicable to many devices, to different devices.

Q. Do you want to just provide that to Mr. Zimmerman?

A. I can do it.

Q. Okay. The second criteria that you've got for symptoms or procedures were anatomically related to the urogenital area and the mesh.

Let me ask you about that. So again, any written source for that?

A. Which one? Say it again.

Q. Criteria 2:

"Symptoms or procedures were anatomically related to the urogenital area and the mesh."

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A. This is established principle of pathology, as I mentioned to you, that I need to know the site of the specimen; I have to know. I have to report where it's coming from. Each pathology report contains site of procedure.

Q. What do you define as the "urogenital area"?

A. Urogenital area?

Q. Yes.

A. Urogenital organs.

Q. And what organs does that include in your definition?

A. Not my definition.

Q. Okay. Well what is it?

A. Anatomically. Vagina, cervix, uterus, adnexa, bladder, ureter, kidneys. In female individuals.

Q. I may not have gotten this list exactly but vagina, cervix, uterus, adnexa, kidneys?

A. Yes.

Q. Did I miss any?

A. That's the general description.

Q. And Carlino obviously involves an

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implantation of TVT. Is it your opinion that any symptoms or procedures that occur in any of those urogenital organs would have bearing on the TVT?

A. It may have bearing on TVT; it may have bearing on her symptoms. It depends, it depends on the scenario. Again, I think we are trying to kind of dissect it, which is difficult to separate.

Q. When the TVT is placed, does it come in contact with the cervix?

A. Not if it's placed properly.

Q. For example, in Ms. Carlino's case, the TVT would not have come in contact with her cervix?

A. No, it shouldn't.

Q. Same question for uterus.

A. Again, if it's placed properly, and doesn't migrate that far, I mean it's...

Q. In Ms. Carlino's case, no reason to think that the TVT would in any way touch or communicate with the cervix?

A. She had hysterectomy at the time of placement, so she had no uterus, no cervix after the mesh was placed.

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Q. And the mesh would not be placed in the area where her cervix or uterus had been, would it?

A. Not normally.

Q. Okay. I just want to make sure, because you qualified that. I mean, you don't have any reason to think that it was placed in the Carlino case, or it would communicate with where the cervix or uterus used to be?

A. No, no.

Q. I'm not trying to be difficult, I don't think anybody at this table thinks that it was. I just want to make sure the record is clear on that.

Same question regarding adnexa.

And in Ms. Carlino's case, the mesh, the retropubic mesh would not be placed in a position that would touch or communicate with that, would it?

A. No, it shouldn't. I mean, if it's properly placed, it shouldn't be in contact or shouldn't be in the area.

Q. Same for the kidneys?

A. Of course not.

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Q. After a hysterectomy is performed, is the -- strike that.

What's a vaginal cuff?

A. It's the top portion of the vagina.

Q. And after the hysterectomy is performed, would the cuff be at the top of the woman's vagina?

A. There would be a vault, so cuff, again, it's a vague term. For us, the pathologists, the vaginal cuff is something which is removed with the uterus, part of the vagina; it can be used in some other work.

But after the uterus is removed, there is a vaginal vault which is a blind vaginal pouch.

EXHIBIT NO. 4: Illustration of a Female Urogenital Organs Post-hysterectomy.

BY MR. COMBS:

Q. Dr. Iakovlev, I just want to use this to make sure we're on the same page of the areas we're talking about.

The Exhibit 4, is that a depiction of a woman who is post-hysterectomy?

A. That's correct. But I wouldn't

call it "cuff", I would call it more of a vaginal vault. So what we use more commonly is vaginal vault.

Vaginal cuff is part which is removed, rather than the one which stays. Again, that is terminology we use as pathologists, use most commonly.

Q. Okay. And whatever we refer to it as, I just want to make sure that we're all on the same page and the record is clear.

What you're calling a vaginal vault, would be the area that is identified as "vaginal cuff" on this diagram?

A. Yes.

Q. And a TVT that was properly placed, would not be in the vicinity of the vaginal vault or cuff; would it?

A. No, it shouldn't be there. Again, provided the cuff or the vault is described properly and provided TVTs staying in the position where it's supposed to be, not migrating.

Q. Again, same question for obturator internus muscle. A TVT that's properly placed, would not pass through the obturator internus,

would it?

A. Unless it was placed like this. I mean, if it was intended to use as transobturator tape --

Q. Bad question. Let me do it better.

Retropubic TVT. A retropubic TVT would not be placed in the obturator internus muscle, would it?

A. Yes, unless it migrates there.

Q. Okay.

A. Because it can migrate.

Q. Okay. It's not placed in the obturator internus, is it, if it's a retropubic?

A. Not intentionally. I'm not a surgeon, but from what I understand, the techniques, I mean, it's placed retropubically rather than laterally.

Q. And a properly placed retropubic TVT is not placed in the puborectalis muscle either, is it?

A. I would have to defer you, if it can be done during the procedure. I would have to defer it to clinical colleagues, to surgeons.

Q. Okay. On the issue of whether a retropubic TVT properly placed would pass through the puborectalis muscle, you would defer it to a urogynecologist or some other medical specialist on that?

A. Yes. Sometimes I do have striated muscle in the resected retropubic meshes. But part of the muscle, I'm not sure.

Q. Okay. So on the obturator internus muscle, that would not be in the path of the properly placed TVT; and on the puborectalis muscle you would just defer?

A. Yes. But as I said, I do receive some excised retropubic meshes, slings with some striated muscle. So in some circumstances, they do cross striated muscle. Normal, not normal circumstance, but they do. I have to break now.

Q. Of course, that's fine. Can I ask one more question before you do?

A. Yes.

Q. I just want to follow up just on the striated muscle issue. The fact that you may have seen striated muscle in a sample from a retropubic TVT, that does not necessarily mean that

it was muscle from the obturator internus or puborectalis?

A. Could have been any of those, could have been migrating to the area. So it would be hard for me to explain it just using microscope. I can only state that there is striated muscle, but in each specific case we would have to go to the records and intraoperative report to see where exactly it was explanted from.

And then maybe go to implantation records to see if it was implanted or had a chance to be implanted in there, or migrated into the area. But each specific case would be specific.

Q. Okay. And on just the Carlino case, you --

A. If I can check with the pathology report, I only check for presence of striated muscle, and in this case, I did not see striated muscle.

Q. Okay. All right. We'll take your break now, thank you.

MR. COMBS: Off the record.

-- RECESS AT 10:24 --

-- UPON RESUMING AT 10:42 --

BY MR. COMBS:

Q. Dr. Iakovlev, I'm going to ask you now about the third criteria that you set forth on page 86 for the clinicopathological correlation.

And would a record that showed that after the revision in December 2010, Ms. Carlino had complete resolution of her pelvic pain and dyspareunia; would that be a record that would fall within the third criteria that you set forth?

A. Not sure. As I said, it describes mainly a decision to excise the mesh. I guess you can put it in that way.

Q. Did you review any records in Ms. Carlino's case that had a finding that after the December 2010 revision, that Ms. Carlino had complete resolution of her pelvic pain and dyspareunia?

A. I have to see what I wrote. I think my record stopped at around 2010, so I don't have records after that. At least it wasn't in the summary.

Q. Okay. And we'll mark this as Exhibit 5.

EXHIBIT NO. 5: Medical Record dated

April 26, 2011 by Ellen Conner, M.D., Bates No. CARLINOS_MOG_MDR00556.

BY MR. COMBS:

Q. And you're familiar that the surgeon who performed the revision for Ms. Carlino in December 2010 was a Dr. Conner?

A. As I said, I don't remember the names of physicians.

Q. All right. Well, I don't think it's controversial. Dr. Conner performed a revision in 2010; this is a record from her office.

And in the second paragraph she says:

"On December 17, 2010, I performed partial removal and revision of vaginal sling ureterolysis, and cystoscopy. This resulted in complete resolution of her pelvic pain and dyspareunia but worsening in her stress incontinence." [As read]

That is a record that you did not have at the time that you made your clinicopathological correlation, isn't it?

A. I don't know. I could have had

it, we need to check with the folder. The date is 2011; there is a possibility I didn't have it.

Q. As we sit here today, do you remember having it?

A. I don't remember. I cannot remember all 80 patients; it's physically impossible. If it's not there, then I didn't have it.

Q. Well, we took a look at the records that are on the flash drive that you gave us, so if it's not on that, that would mean that you didn't have it for your clinicopathological correlation?

A. Say it again.

Q. If it's not on the flash drive, that means that you did not have that for your clinicopathological correlation?

A. That's correct.

Q. Dr. Iakovlev, are you familiar with the article, "Histopathology of Excised Mid-urethral Sling Mesh" published by Hill in 2014 in the International Urogynecology Journal?

A. Yes, I read it.

Q. And when did you first become

aware of that paper?

A. Relatively recently.

Q. Was that during the deposition in September when David Thomas from my office deposed you in the Mullins case?

A. No, it wasn't during deposition. I don't remember exactly what's the circumstances, but I became aware of it.

Q. That's not on your reliance list in the Carlino case?

A. No. As I said, I just came across it relatively recently.

Q. And you're not relying on that paper for your opinion in Carlino, are you?

A. Retrospectively, I wouldn't rely on it because they didn't do analysis the way I do. They didn't score foreign body response.

They scored only chronic, and then they used terminology which was unconventional about fibrosis. I mean, it seems like authors didn't know what was published before in meshes.

Their rate of inflammation was very different from previous papers. So there are some quite questionable aspects in that paper.

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Q. And so again, my question was: You're not relying on that paper for any part of your opinion in Carlino, are you?

A. No, I wouldn't. I mean, when I was preparing the expert report, I was not aware of it. And now in retrospect, I wouldn't rely on it.

I mean, I would consider what people are doing, what people are trying to do, but it wasn't done appropriately enough to be a reliable source.

Q. And the authors of the Hill paper are from the Cleveland Clinic; aren't they?

A. I don't know.

Q. You don't know?

A. No.

Q. It's published in the International Urogynecology Journal; isn't it?

A. Possibly, I don't remember.

Q. I'll represent to you it's published in the International Urogynecology Journal; is that a reputable journal?

A. It's not a high impact journal, but it's a journal.

Q. Do you rely on other articles from

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that journal on your reliance list?

A. I read some articles from the same journal; they publish quite a number of articles.

Q. The pathologists in the Hill paper were blinded, weren't they?

A. Yeah, the pathologist was blinded --

Q. What does that mean?

A. -- to the cause of explantation of symptoms.

Blinded means that you don't know specific piece of information. Whoever is assessing a feature, is not aware of its specific feature, so he's blinded.

Q. What is the purpose of blinded?

A. To reduce bias or reduce possibility of a bias.

Q. And the review that you've conducted in the Carlino case, by definition that's not blinded, is it?

A. I think we are mixing apples and oranges. Are we talking about research or are we talking about diagnostic assessment?

Q. Either. The review that you did in Carlino is not blinded, is it?

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A. How would you like to go to hospital with your own problem and ask everybody to be blinded of your current history? You're mixing things unmixable.

The diagnostic process cannot be blinded by definition. It's based on full understanding of the history and knowledge of previous investigations.

Blinded is only approach used for research purposes. So let's not mix it; let's make it clear. You are trying to mix something which is not mixable.

Q. And the review by the pathologist in Hill was blinded, wasn't it?

A. That's what they say in their methods.

Q. Do you have any reason to think it wasn't?

A. No.

Q. And the review that you do for the Carlino case, it's not blinded?

A. I think I answered that question. Twisting things, and you're trying to mix things which are completely unmixable.

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Either we're talking about research or we talking about diagnostic process. Choose.

Q. Okay. Again, my question. The review that you did in the Carlino case, it's not blinded, is it?

A. It's wrong question. It's incorrect.

Q. Okay. Do you refuse to answer the question?

A. I'm not refusing it. I mean, this question is completely incorrect. This misrepresents the whole medicine.

Q. Okay. So what were the parameters that the pathologist in the Hill case was blinded to?

A. Now let's pick. Are we talking about research or diagnostic process?

Q. No, I get to ask the questions here. So that's my question.

My question is: What were the factors that the pathologist in the Hill case was blinded?

A. In the Hill case was not --

Q. Strike that -- not the Hill case, the Hill paper?

A. In the Hill paper, it was not a

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diagnostic process; it was a research project. If we want to talk about research project, we can. Again, it's going into general opinions, but we can talk about it. I can talk about it.

But let's not mix diagnostic process because it's completely separate process. It has to be completely open, not blinded. You cannot use blinded, because it would be a malpractice to do a blinded assessment of a diagnostic specimen.

Q. For any of the clinicopathological correlations that you do, are they ever blinded?

A. No. That's why I do clinicopathological correlation, because I'm trying to become aware of all information available.

Q. And so at the time that you do -- strike that.

At the time that you did the Carlino evaluation slides, you were aware of her -- the medical conditions that she presented with at the time of her revision?

A. Yes. I intentionally requested materials, clinical records, to become aware of as much clinical information as possible. Because that's the way diagnostic process is done.

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Q. And in the Hill paper, they were reviewing explanted meshes and did not know the symptoms that were presented at the time of the explantation; isn't that correct?

A. Now we are switching from the area. We are talking about diagnostic process, now you're going back and forth to research. I think it will be very confusing in the record.

Q. Dr. Iakovlev, Mr. Zimmerman is here to worry about the record. Here is my question.

My question is: In the Hill paper, the pathologist was blinded to the reason for the explantation, weren't they?

A. Yes. As a research, you want to be blinded. But that would be completely separate process, and the pathologist was not assessing samples for diagnostic purpose.

But they had a specific research question; that's why they were blinded.

Q. And you said that you had a criticism of the way that the pathologist in the Hill case scored the foreign body reaction; is that correct?

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A. Yes. They didn't, actually. They didn't score it.

Q. And you said that you had a criticism of -- I'm paraphrasing -- but the terminology they used to describe fibrosis?

A. That's correct. Because fibrosis had been described in hernia meshes decades ago, in term of bridging, fibrosis was used in that. But in the Hill paper, they used some obscure definition of fibrosis. And it wasn't really clear what they were using as a criterion for fibrosis at all.

Q. And that the rate of inflammation was different. That was also a criticism that you had of the Hill paper, is that correct?

A. That's correct. I think the difference was up to 30 percent, so with the previously published Smith --

(Reporter sought clarification).

A. Smith et al. paper.

Q. And did you have any other criticisms of the methodology of the Hill paper?

A. There are things like they didn't separate clinical symptoms into smaller categories.

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There are a few smaller things, I just don't remember now.

But when I went through it, it's obvious they didn't spend as much time in the field as I did. So I learned a little bit more, because I was just exposed to much larger volume and I've been in the field for much longer time.

Q. How many meshes did the pathologist review in the Hill paper?

A. I don't remember now. But it was smaller than my collection.

Q. Do you know the pathologist from the Cleveland Clinic that did that review?

A. No.

Q. How do you know how many meshes that pathologist had reviewed?

A. Well, it was written in the paper, the methods.

Q. Strike that.

Do you know whether the pathologist from the Hill case or the Hill paper had ever reviewed any meshes other than the meshes that are the subject of the Hill paper?

A. Well, the terminology they used

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was clear, that they are not aware of many publications which were published for hernia meshes; they just didn't use it. And I don't think they used it as a reference material as well.

Q. And so my question again is: Do you know whether the pathologist from the Hill paper had reviewed any other meshes, other than the ones that are the subject of the Hill paper?

A. I don't, I don't know. It wasn't clear to me that they review, their general -- their general understanding of the mesh body interactions wasn't quite there.

Q. I just want to make sure that my question has been answered. You don't know how many meshes the pathologist in the Hill paper has reviewed; do you?

A. It's written in the methods what was written. What they reviewed beyond that paper, that would be a different question, but --

Q. And you don't know the answer to that question?

A. I don't know.

Q. For the papers that you have published regarding mesh complications, has the

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pathology been blinded in any of those papers?

A. I think we're drifting into general questions again.

Q. Has the pathology been blinded in any of those papers?

A. Which papers?

Q. Any paper that you have written regarding mesh complications.

MR. ZIMMERMAN: Did you say "written"?

BY MR. COMBS:

Q. Yes. That you're an author on.

A. Depends on the feature. I mean, sometimes when I analyze it, then I know the answers after that, because I write the paper.

When I assess specific feature, it's not in front of me, so I'm blind for a specific feature. It depends, depends on paper, depends on the question.

Q. Here is my question. For any of the papers that you've written regarding mesh complications, was the pathology blinded?

A. For some features, yes.

Q. Was it blinded for all features?

A. What do you mean, for all

Page 72

features?

Q. Is there any paper that you've written regarding mesh complications, in which you describe in the methodology of the paper that you were blinded?

A. Yes.

Q. What were they?

A. Well, even in the degradation paper, the latest paper, when I was measuring the sequence of degradation bark, I had no idea what the reason for the explantation was. Then I could extract it when I was putting the paper together. It was available to me, but when I was measuring it, I wasn't -- it wasn't in front of me, I wasn't aware. Basically, I was blinded for that specific step.

But when you read the whole paper, as an author I had to provide all the information. So at certain stage, I pulled this information up.

Q. Do you agree that in the Hill paper --

A. For some papers, for some features in some papers, I used second pathologist. Again, we're drifting into general questions, I think we

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need to stop now.

MR. TRUNK: I am going to second that. There is an agreement in place that this is not to deal with general areas. There's an agreement that was discussed before Judge New, and an agreement was reached between the parties not to go into general -- I've let it go on for a long time now, but there's nothing specific to Carlino with respect to these questions.

BY MR. COMBS:

Q. Doctor, let me ask you some questions about the medical records that you've reviewed for the Carlino case.

Did Ms. Carlino suffer from pelvic pain prior to the implantation of the TVT device?

A. She had back pain.

Q. So your answer is that Ms. Carlino had back pain prior to the implantation of the TVT device?

A. Yes, that's correct. I put it in the summary.

Q. Did Ms. Carlino have pelvic pain prior to the implantation of the TVT device?

A. As far as I can see from my

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summary, that information wasn't there. I didn't see it.

Q. If Ms. Carlino suffered from pelvic pain prior to the implantation of the TVT device, is that something that you would put in your summary of clinical records?

A. Most likely.

Q. All right.

MR. COMBS: Let's mark this as Exhibit 6.

EXHIBIT NO. 6: Operative report for Sharon Carlino dated August 18, 2005 by Andrew Blechman, M.D., Bates No. CARLINOS_JSUMC_MDR0052 - MDR0054.

BY MR. COMBS:

Q. Dr. Iakovlev, I've handed you what's been marked as Exhibit 6. And is that the operative report for Ms. Carlino's implantation surgery?

A. Yup, looks like it.

Q. And you can take a second to review that if you'd like.

A. (Witness reviews document).

Q. Was one of the preoperative

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diagnoses for Ms. Carlino pelvic pain?

A. Yes, that is there.

Q. And was that also one of the postoperative diagnoses for Ms. Carlino?

A. Postoperative diagnosis is same, so I guess it's the same.

Q. And that would be pelvic pain that Ms. Carlino had prior to the implantation of the TVT device?

A. Yes, that's correct.

Q. And that record is not something that you included in your clinicopathological correlation?

A. I did review it, obviously, because as we talking about pelvic pain, there are other reasons for pelvic pain, like menorrhagia, fibroids, and surgery was done at the same time.

So when I was reviewing, I thought that it's not significant to put in the summary. Summary is more of a guide for me.

Q. And that finding that Ms. Carlino had pelvic pain prior to the implantation of the TVT device, is not included in your summary, is it?

A. No, I didn't put it in my report.

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I had probably reasons to believe that it was not related to the mesh.

Q. If Ms. Carlino had a mesh revision, would that be something that would be included in your clinicopathological correlation?

A. Sometimes I saw many that I do not include each of them. I try to include major events in the summary.

Q. How many mesh revisions has Ms. Carlino had?

A. As I said, I mean, I try to include any major events in the summary. So if there was some minor clippings or how they say office excisions, it could have not included them.

Q. Do you know how many revisions to pelvic mesh that Ms. Carlino has had?

A. As I said, right now I don't remember all records; she had at least one. So I could receive the specimen. There could be other smaller excisions, or excisions after that date. Either I'm not aware, or I don't remember now.

Q. If there was a mesh revision that you thought was relevant to Ms. Carlino's clinicopathological correlation complication, you

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would have included it in your summary?

A. If I thought that something -- well, if the material is available to me and I think it is important for me for clinicopathological correlation, I would've included it in the summary.

Q. And it is not a secret, Ms. Carlino had an explantation on November 26, 2007. You did not include that in your correlation, did you?

A. Either I didn't have that record, or it was not significant for my correlation. So I don't see it in the summary.

EXHIBIT NO. 7: Operative report for Sharon Carlino dated November 26, 2007, by Dr. Blechman, M.D., Bates No. CARLINOS_JSUMC_MDR00125 - MDR00126.

BY MR. COMBS:

Q. Dr. Iakovlev, I've handed you what's been marked Exhibit 7, which is an operative report from November 26, 2007 for Ms. Carlino.

At the bottom it's got the Bates number from Jersey Shore Medical Center. This would be one of the records that you would have had to

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review Ms. Carlino; isn't it?
A. Well, I could, I could have not; I don't know. I don't remember now exactly each page I had. If it's not in the record, it wasn't there. If it's there, then I reviewed it.
Q. Again, I haven't gone through every page of the record, but I assume it's there because you do have records in your flash drive from Jersey Shore Medical Center. So I assume it was there; if it's not, it's not.
This would be a procedure that you did not rely on as part of your clinicopathological correlation?
A. Well, rely, not rely, summary is just a summary. Something like in bullet format which describes a general idea. I mean, if I review the records, sometimes I include it, sometimes I don't.
Q. It's fine if you need --
MR. COMBS: Let's go off the record for a second.
-- RECESS AT 11:15 --
-- UPON RESUMING AT 11:20 --

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BY MR. COMBS:
Q. Dr. Iakovlev, before the short break, you had taken a second to look at the November 26, 2007 document that's marked as Exhibit 7.
That's not set forth anywhere in your report, is it? No mention of that document?
A. It wasn't included. If I saw it, if it was included in my records I could review, then probably didn't make that much of a difference, so I didn't include it.
But as I said, the summary is not a comprehensive review of the records. Sometimes I include things; sometimes I don't. Depends on situation.
Q. You may think there is more motive here than there is. There was no pathology with this.
And I just want to make sure that you're not relying on this as part of your opinion. If you are, I'm going to ask you questions about it. If you're not relying on it, I don't want to ask anything more about it.
A. See, I would have to think. I

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mean, when I go through records they all go through my head. If I don't include them, it doesn't mean that I don't rely on them.
I pretty much extract all the information I can. But sometimes it's not enough for me to put in the summary. Sometimes I get so much records, I mean, it's impossible to make an attempt to describe everything.
Seems to be a small excision, or a small piece. I'm not even sure if it generated any specimen, as I said.
Q. There was no pathology?
A. It's pretty common. When they get eroded, they erode multiple times. It's recurrent erosion.
Q. Okay. And Exhibit 7, there is no reference to it in your report?
A. I didn't include it.
Q. And as we sit here today, you're not relying on this for part of your opinion in the case.
MR. ZIMMERMAN: Misstates his prior testimony. Objection.
THE WITNESS: If I saw it, it was in my

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head, I am relying on it. I just made a note that it's recurrent erosion, wasn't big enough to be included.
So I do rely on it. Whatever I read, whatever I learn about the case, I do rely. It leaves trace in my head.
BY MR. COMBS:
Q. Okay. Do you know what Ms. Carlino's clinical course was after this revision?
A. After 2007?
Q. Yes, sir.
A. (Witness reviews document).
"She presented in 2010, feeling something sharp in the vagina. There was a palpable mesh and she was referred to a surgeon for recurrent erosion."
So, as I said, I mean, the erosion recurred.
Q. Now, do you have any information regarding what Ms. Carlino's condition was between November 2007 and 2010?
A. I don't remember all records now.

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I mean, what I have right now is just a summary so -- and to me, as I said, as a pathologist, I'm not making a comprehensive summary of the records. I'm extracting information to interpret the pathology. I was aware of what going on, going through the records, if that's the question.

Q. During the period of 2007 to 2010, do you know whether Ms. Carlino was continent?

A. I don't remember all the details in between. As I said, right now, I just have the summary.

Q. During the period of 2007, 2008, 2009, do you know whether Ms. Carlino had any pelvic pain?

A. (Witness reviews document).

So what I extracted from the records was discomfort, sensation of something sharp --

Q. So my question was: For the period of 2007, 2008, 2009, do you know whether Ms. Carlino had pelvic pain or dyspareunia?

A. I didn't. I mean, it wasn't my purpose; I'm not a clinician. I was extracting information which is relevant in my specimen

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understanding.

I mean, you would probably need to -- I would defer all of this then to clinical colleagues who analyze the history and details, clinical.

Q. Okay. When you say a clinical person, are you talking about a urogynecologist or someone who's treating Ms. Carlino for that condition?

A. Either treating or is a specialist, clinical specialist, yes, that's correct.

Q. All right. And so on issues like that, you would defer on?

A. Not defer entirely. I just say that the clinical specialists would be more interested in smaller details of clinical presentation and development.

To me, clinical history is more of a background to understand my pathology. It is a little bit different view in that I need major facts in the history.

Q. I'm sorry, major?

A. Yes, major facts, major developments rather than small details in the

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development.

Q. Okay. Ms. Carlino's implant was in 2005, wasn't it?

A. Yes. August 18, 2005.

Q. Now, do you know whether Ms. Carlino was continent between 2005 and 2010?

A. Wasn't my purpose. I mean, when I was going through records, I could see if she wasn't or she was. Sometimes I include it but most of the time I don't include it.

Q. Okay.

A. Because I'm not assessing the sling for its effectiveness. I'm assessing the complications which developed after its placement.

Q. And as we sit here today, you're not aware of whether Ms. Carlino was incontinent between 2005 and 2010, are you?

A. That wasn't my purpose. I wasn't focusing on that.

Q. And you have on your chronology that in December, Ms. Carlino had an explant; is that correct?

A. Yes.

Q. And I think this is self-evident,

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but let me make sure the record is clear on it.

You would have played no role in any way in regard to the treatment or pathology regarding that explant as a treating physician?

That's a terrible question. Let me start over.

You weren't a treating physician for Ms. Carlino, were you?

A. No, I was not a treating physician.

Q. And you are not a treating pathologist for Ms. Carlino, are you?

A. The pathologist -- I wasn't the primary pathologist, that's correct.

Q. I mean, Dr. Govil, the Jersey Shore University Medical Center, would have been the pathologist that would have done the read contemporaneous to the explant?

A. Yes. There was a pathologist, yes. I would have to see the pathology report to see the names and exact details.

Q. I'll represent to you it was Dr. Govil.

And your review of the pathology for

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Ms. Carlino would have been in June 2015, four and a half years after the explant?

A. Yeah, that's correct. I was a consultant in this case. I wasn't the primary pathologist.

Q. And so you would have played no role in preparing the specimen from that explant for pathological review?

A. Could you rephrase the question?

Q. Yeah. I understand your criticism. Let me try to do better.

There was a pathology review that took place in December of 2010, and I'll represent to you it was done by Dr. Govil.

You would have played no role in preparing the specimen or the slide for that review in 2010?

A. If you're asking if I prepared the slides for that review, no. The first time I was involved in this case and had the material was 2015.

Q. And do you know how the tissue was handled prior to your receiving it in June 2015?

A. I created the diagnostic lab --

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oh, sorry.

-- INTERRUPTION IN THE RECORD --

-- RECESS AT 11:20 --

-- UPON RESUMING AT 11:30 --

BY MR. COMBS:

Q. Dr. Iakovlev, before we took that break, I was asking you about the preparation of the specimen from the 2010 surgery.

You didn't play any role in handling that until 2015; did you?

A. That's correct.

Q. And how was that tissue processed?

A. It is the standard way of processing tissues, also, diagnostic laboratory.

Q. Okay. How is it processed?

A. Tissue is fixed in formalin, and then it's grossed, and then it's placed in the cassette, and then it goes through a processing machine, and then it becomes embedded in paraffin blocks, sectioned, stained, cover slipped.

(Reporter sought clarification).

A. Cover slipped.

Q. You and I are both quiet. I'm sure it's difficult for her.

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Was the tissue dehydrated?

A. Yes, it was.

Q. Cleaning agent -- sorry. Clearing agent added to it?

A. What do you mean "clearing agent"?

Q. Was xylene added to it?

A. Yes.

Q. And was fixative added to it?

A. Yes, of course.

Q. And what was the fixative that was added to it?

A. Formalin, it begins with formalin.

Q. And who added the formalin?

A. Some staff person.

Q. And you wouldn't know any person who had any role in preparing that specimen, would you?

A. No.

Q. Was it embedded in paraffin?

A. Of course.

Q. And why?

A. Pardon?

Q. Why?

A. Why? You need to embed it into

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some form of median to section in the microtome. It has to be supported by something in order to be, to be cut.

Q. And is that so that the tissue will be stiffer so the microtoming process can occur?

A. Not stiffer. Tissue would be held by paraffin.

Q. As a result of the dehydration and fixation of this specimen, would it be hardened?

A. To a degree, yes.

Q. And would it be smaller?

A. To a degree, yes.

Q. You would have shrinkage of the specimen?

A. Well, depends on what -- it only shrinks when you have water in it. So something which is solid, without water content, will not shrink because shrinking comes from dehydration.

So when I dehydrate, I extract water and the tissue shrinks. There is a degree of shrinking due to formalin, but it's much minor, smaller.

Q. What would be the degree of

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shrinking that would occur to Ms. Carlino's tissue after the specimen was processed?

A. Depends on what part of the specimen we're talking about. Mesh fibers wouldn't shrink at all. Dense fibrous tissue wouldn't shrink much.

It would be more of a loose areas, more edematous areas would be shrinking more. It all depends how much water is in the material. Polypropylene doesn't have much water except for degraded part.

Q. Okay. Obviously, I'm a lay person. So is it fair to summarize that tissue would shrink more based upon the amount of water it had in it prior to the processing?

A. No, the amount it had in the body.

Q. In vivo?

A. In vivo. So something has a lot of water, like edematous tissue is placed in alcohol, the water would be extracted and replaced by alcohol. Some of it will be extracted; some of it will be replaced.

So some of the spaces will contract, some of the spaces will just remain open, empty,

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because the water is being drawn out. Also depends on the rigidity of adjacent structures, like collagen fibers, or arteries, or mesh fibers.

Q. The polypropylene would not shrink any as a result of the dehydration process, would it?

A. No. Polypropylene itself wouldn't shrink, that would be, I mean, if there is no water in there, there wouldn't be any mechanism to shrink it.

Q. And the collagen would shrink some, but not as much as the edematous tissue?

A. Collagen molecule itself, wouldn't shrink. But the spaces between collagen fibers would shrink. And it depends how much space in it, then there would be more or less shrinking.

Q. And the edematous tissue would then shrink more?

A. Edematous tissue what? Sorry?

Q. Would shrink more than the collagen?

A. Yes. Again, to a degree. Depends on adjacent structures, because if there is a large structure which is holding the shape, or if it will just provide an empty space.

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Q. And specimens -- strike that.

There is a procedure by which you can take a specimen and pin it to the board to make it retain its integrity and shape, isn't there?

A. Yes, but we're talking about something else. It's pinned before it's being fixed. So if we're talking about dehydration or we talking about formalin fixation?

Because pinning is done for specimens like stomach, for hollow organs which normally have rounded configuration. So you would have to have some force to keep it flat. So that's the main purpose of pinning.

Q. That would not have been done to this specimen?

A. Mesh is not a hollow organ; it's not a stomach.

Q. So it wouldn't have been done to this specimen, would it?

A. There wouldn't be a purpose for that.

Q. So it wasn't done, was it?

A. No.

Q. Now, the treating pathologist was

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Dr. Govil, and what did Dr. Govil find regarding this tissue?

A. Can I see his report?

Q. Sure. We'll mark this as Exhibit 8.

EXHIBIT NO. 8: Pathology Report dated March 3, 2006, by Dr. Govil, Bates No. CARLINOS_JESUMC_PAT00766 - PAT00767.

THE WITNESS: So signed, Sushama Govil, final pathology diagnosis page says:

"Fragments of fibroconnective tissue with mild chronic inflammation and foreign body giant cell reaction to foreign material comma, vaginal mesh." [As read]

BY MR. COMBS:

Q. And is that the same finding that you made?

A. Yes, it is the same. This is a summary of findings.

Q. And so the finding that you made in your pathology report would be consistent with "Mild chronic inflammation and foreign body giant cell reaction to foreign material, vaginal mesh"?

A. That's what I describe.

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Q. And Dr. Govil made no finding to dyspareunia, did he or she?
A. That's what his findings are. He is given clinical history, mesh erosion, dyspareunia, a revision of sling cystoscopy.
So he's asked question: "What is wrong with the tissue which is causing these symptoms?"
And his answer is: "Fiber connective tissue with mild chronic inflammation, foreign body giant cell reaction to foreign material."
That's an abnormality he sees in the tissue which was received for treatment of erosion dyspareunia.
Q. And the clinical history that he received, that's something that he would have been informed by Dr. Conner?
A. Clinical history in the surgical pathology reports copies what is on the requisition. So usually it's entered by excision clerk or secretary. It's a copy of what was provided with the specimen.
He could have more information, through personal communication, or just review of the records, I don't know.

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But I can say for sure that this was provided on the requisition with the specimen.
Q. And Dr. Govil makes no finding regarding urinary symptoms?
A. He's not given it. I don't know if he knew about it, I mean...
Q. Okay. So my question is Dr. Govil makes no finding in the final pathological diagnosis about urinary symptoms; does he?
A. Not directly.
Q. And Dr. Govil makes no finding regarding degradation in the pathology report, does he?
A. No.
Q. Dr. Govil's diagnosis that he found mild chronic inflammation; you told us that that's consistent with what you found?
A. Yes, if we go through my pathological findings.
So I describe mostly foreign body type, because it was more pronounced rather than non-specific chronic inflammation.
Fiber connective tissue, that's what I describe as scar. And my focus was mainly on

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foreign body type, because in my assessment, is more pronounced than chronic, no specific.
Q. Okay. And so Dr. Govil's finding that the inflammation is mild, that would be consistent with your finding in regard to Ms. Carlino's pathology as well?
A. Yes. It wasn't as pronounced as foreign body type reaction.
Q. What did you do with this specimen after you got it? And let me just, again, you know I'm not trying to be secretive here.
I think there might be a mistake under the pathological findings. And I just want to ask you about it to make sure I understand.
Under the "Pathological Findings" you said:
"I received one H&E stain slides and ten unstained slides labeled JS10-13237, Meridian Health."
That's not actually correct, right? I mean, didn't you -- you cut the ten slides?
A. I'd have to see chain of custody from what I receive and what I should.

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Q. Okay. So let me ask you, maybe I'm mistaken on that. Did you receive 11 slides from Jersey Shore?
A. I'd have to see chain of custody from what I received. It could probably was from Steelgate.
MR. COMBS: Let's go off the record for a second.
EXHIBIT NO. 9: Chain of Custody Form dated October 8, 2015.
BY MR. COMBS:
Q. Dr. Iakovlev, we went off the record for a second and discussed this. And I'm now handing you what's been marked as Exhibit 9. Is that the chain of custody form from you to the defense lawyers in regard to Ms. Carlino's specimen and slides?
THE WITNESS: Yeah, that's correct.
BY MR. COMBS:
Q. Okay. And does it reflect that what you got is that you got one slide from Meridian Health, which was stained with H&E. And then you've got ten slides which St. Michael's cut regarding Ms. Carlino's tissue?

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A. Yes. I received the block and then I asked them to cut ten stain slides. I think there was agreement with the defense counsel to cut ten stain slides.

So when I was analyzing, I had one H&E and ten stains. So the wording wasn't reflecting the whole story.

Q. I understand. Just so the record is clear, or the reality of what happened is, you got one stain slide and you got the block, and then ten slides were cut from the block?

A. Yes.

Q. And those ten slides that were cut from the block, would have been cut sometime in 2015 at St. Michael's?

A. Yes.

Q. And I would like to be able to forego a lot of questions about the process of cutting the slides.

So let me just give you kind of a long statement, and then you can either agree or disagree and we can just go from there, but I want to cut out some of this.

When you were deposed in September of

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2015, you talked about the process of cutting the slides at St. Michael's. And in a prior deposition you had provided us with the protocol from St. Michael's.

And so all I want to do is just establish these would have been cut same way, same protocol?

A. That's correct.

Q. So the slides that would have been cut at St. Michael's for Ms. Carlino's mesh, would have been cut the same way that the other slides had been cut that you have been deposed about?

A. That is correct.

Q. And they would be cut pursuant to the protocol that you previously provided us of the St. Michael's slide cutting process?

A. Yes. Standard operating procedures.

Q. Okay, thank you.

Now, after the specimen was provided to you, did you take any efforts to clean the formalin protein shell off the explant?

A. I'm sorry. There is no such thing as protein formalin shell.

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Q. So would the answer be "no"?

A. It doesn't exist.

Q. So you took no steps to clean that?

A. Of course not.

Q. All right. And did you receive any analytical chemistry regarding Ms. Carlino's mesh?

A. What do you mean?

Q. For example, in other cases in which you've been involved, the specimen has been sent to an analytical chemist. Say, for example, Dr. Jordi, or somebody like that, an analytical chemistry has been done regarding the specimen. Did that occur in this case?

A. I don't think I ever had results of those analysis, and I never relied on them.

Q. So to the best of your knowledge in this case, no analytical chemistry was performed in regard to Ms. Carlino's mesh?

A. I don't know, and I wouldn't ask.

Q. You don't know whether the molecular weight of the mesh in Ms. Carlino's sample decreased, do you?

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A. I think you're asking questions of tests I couldn't perform, and I don't do it.

Q. Okay. Just so the record is clear, you don't know if the molecular weight of the proline in Ms. Carlino's specimen had decreased, do you?

A. No, I don't test for that.

Q. And you don't know whether the tensile strength of the mesh in Ms. Carlino's specimen had decreased, do you?

A. No, I didn't measure.

Q. I want to ask you kind of another windup question and maybe we can dispense with some of the questions on that.

I want to ask you whether any scanning electron microscope or transmission electron microscope was used in this case, or whether everything was just taken with your standard microscope.

So that's what I wanted to ask you. Were all of the photographs that you took in this case, based upon your use of the light microscope?

A. That's correct.

Q. No SEM or TEM used in this case?

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A. No. These are all research techniques. They have only very narrow applications for diagnostic pathology.

Q. All of the slides related to Ms. Carlino's explant -- strike that.

You wouldn't have prepared any of the slides related to Ms. Carlino's explant, would you?

A. What do you mean?

Q. That would have been done by someone else?

A. Of course.

Q. That would be done by a technician?

A. That's correct.

Q. Who is that technician?

A. We have like 20 technicians in the lab, and some procedures are done by one technician, some procedures done by a different technician.

Q. So you would not know that person?

A. I know all of them, but I don't know who exactly did on that specific day.

Q. Fair enough. You don't know which specific technician prepared the slides for

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Ms. Carlino?

A. Probably there are several. Different steps are done by different technicians.

Q. There were several different stains used with Ms. Carlino's slides; who picked those stains?

A. I did.

Q. Dr. Iakovlev, I want to go through the slides now. And I'm going to follow pretty much the same procedure for all of them. What I want to do at this point is find out what you're going to say at trial about these slides.

So what I'd like to do is, is to go through them one after another, and I'm going to ask you repetitive questions, but the goal of all these questions is just to find out what it is you plan to tell the jury in the Carlino case using this slide. That's what I'm here to do.

So, let's just start with, just to establish on the record, in Carlino you've got figures SC-1 through 18; is that correct?

A. That's correct.

Q. Page 91 to 108 of your report?

A. That's correct.

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Q. Are all these pictures, on pages 91 through 108 of the slides that St. Michael's processed?

A. I had one H&E slide already stained. I could have taken some pictures of the H&E slide I had already.

All the other stains, they would be done at St. Michael's. For H&E could be either slide, it depends. Some areas could have been photographed on one slide than the other.

Q. Okay. So for the photographs that are labeled as being H&E stained, those could be either from the original slide that you received from Jersey Shore, or from the slides prepared by St. Michael's?

A. That's correct. There wasn't much difference.

Q. All right. So let's go to SC-1. What is it that you're going to tell the jury about SC-1 in this case?

A. Bridging fibrosis scarring, halo, chronic foreign body type inflammation around the fibers.

Q. What else?

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A. That's about it.

Q. Now, how big was the explant in Ms. Carlino's case?

A. Oh, largest dimension was 2.4 centimeter.

Q. And what part of that explant does this -- strike that -- does this photograph represent?

A. One of the flat parts, not curled.

Q. And do you have a picture of the gross specimen?

A. I do. I almost always -- well, I always take pictures. I didn't include it here, but I do take photographs of all gross specimens.

It depends. If it's demonstrative of something, I include it in the report. I guess I didn't include it in this case, but I do. It's probably one photograph I didn't include on this thumb drive; I do have it.

Q. Okay. Just obviously you don't have it with you here today. Would you just be able to provide that to Mr. Zimmerman and he can forward it to us?

A. Yes. But I have a description, if

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we open my --
MR. ZIMMERMAN: Your St. Michael's?
THE WITNESS: No, I don't -- no, I wouldn't have a gross description, because I didn't have a gross specimen, that's right. That's why I didn't have it, sorry.
So answer is, I did not have a gross specimen, therefore, I didn't take a gross photograph.
BY MR. COMBS:
Q. Okay. Now, what portion of the explant is this photograph taken of?
A. As I said, one of the flat portions.
Q. I mean, can you tell us? I mean, can you diagram it for us?
A. What do you mean?
Q. Well, how big is this, the photograph on SC-1, how big is that in vivo?
A. Oh, I can estimate, around 9 millimeters. Anywhere between 7 to 10 millimeters; somewhere in that ballpark.
Q. Okay. So somewhere between 7 to 10?
A. Maybe 6 to 10.

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Q. Okay. And would you be able to tell us what part of the explant this picture is from?
A. What do you mean? Lateral, medial?
Q. Would you be able to draw? Could you draw for us --
A. It wasn't oriented. As I said, I had a flat portion, and one portion which was twisted.
Where exactly was it in the body and exact orientation, would be impossible to restore.
In some specimens, some features point where one end is and where the other one -- in that specific specimen, there are no anatomical landmarks.
Q. So in regard to the slide you photographed in SC-1, you would be unable to tell us where that was in vivo?
A. You mean medial, lateral?
Q. Yes.
A. No.
Q. And would be unable to tell us what part of the explant that came from?

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A. What do you mean, what part of explant?
Q. Well, if I gave you a sheet of paper and I asked you to diagram, here's the explant, show me where this comes from, you would not be able to show that?
A. Depends on orientation. Because as I said, this is a flat portion, and there is a twisted sort of deformed portion.
So if picture is taken well enough, I can see where the flat portion and where the twisted portion is. So then I would provide you the most likely location.
Q. Okay. But you don't have that for this case, do you?
A. I didn't have a gross specimen.
Q. So you would be unable to tell us where this was in the specimen?
A. If you give me a picture, I can try to restore its position.
Q. But you don't have the picture, right?
A. No.
Q. Okay. Dr. Iakovlev, I wanted to

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ask you a question about the photography in SC-1. Was there any enhancement of the colors in that?
A. No, I don't think so. I have to play sometimes with some images which are taken at really high magnification or with polarized light, because it's too dark. But this one, no.
If it's just straight, normal magnification I just don't do anything.
Q. All right. And the reason I'm asking you that, is that the colors -- I should make sure the record is clear.
I mean, the picture on the top and the picture on the bottom in SC-1, that's the same piece of mesh, right?
A. Yes. But see, this one is altered. So when I save it, the program saves the whole thing. So maybe it changes color space, I don't know.
Q. So, for example, on the bottom picture of SC-1, you have "inflammation" drawn in. You have "normal tissue" drawn in.
And those are things that you've superimposed on top of the picture?
A. Yes.

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Q. And what I'm specifically asking you about is, see the colors are different on the top and bottom picture.

A. As I said, the original here is just extract from the scanned image. This one is saved later on. So the first image is created by different software; second image is created by Photoshop. It might change color space, or in this specific case, it probably did.

Q. Okay. And I'm not insinuating anything here, you did not intentionally change the color on this slide?

A. As I said, I don't remember. Sometimes I have to correct some colors, because it turns out green, or pink, or -- it all depends on the picture. But I don't believe there isn't -- I would change anything here, because original picture was all right.

Q. Okay. When I'm looking at the slides, how do I know when it's one that you've changed the color on?

A. If any changes are done -- well, I mean, it depends on the scenario. If white balance is not correct to begin with, I have to alter the

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non-labeled copy as well.

If it doesn't come out white, background is not white, if it's pink or green, as I said, I have to correct white balance first, then save the original image, then do my labeling and then save it as a copy of the mesh.

So the alterations of the image can -- well, not alterations, adjustments of the image may happen either at this stage, or only at the labeling stage. It depends on the scenario, on the image.

Q. So again, because you were using your hands to point, it would be hard for the record to reflect this.

Okay. So the color adjustment could occur on the top image, which would be the original photograph of the image?

A. So for the original image, I have to do white balance. I have to do white balance, I have to make the best way possible to make it look like it looks in the microscope.

So this image can be adjusted. So then when I'm satisfied with the image, with the original image, that the white balance is correct,

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that the corners are not darker, or middle portion is not light. So when it's flat, when it's acceptable, then I superimpose labeling.

And then it's saved in a different software.

So the first software is different when you extract the image, and it's second software when I put -- I use Photoshop, is different.

Q. And so the first picture, what software are you using to take it? The one that's on top?

A. Pardon?

Q. On the top picture --

A. Yes?

Q. -- what software do you use for that picture?

A. What software?

Q. Software?

A. Oh, software. Sorry, okay. See, when images are scanned, I think they are scanned with, again it depends, if it's scanned image, they scan by a Puret system.

If it's image taken by photograph, it comes with Canon software, I use Canon camera.

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Then when I adjust images, when I adjust images initially, I adjust some of them in Canon software.

The Puret does have some adjustment features embedded usually. And then when I put labels and cropping and other things, then I use Photoshop.

Q. And here is my question. For the 18 pictures that are in the Carlino report, or SC-1 through SC-18, is there any way I can know whether that image has been adjusted?

A. They had to be adjusted, at least for white balance. I mean, there's no way you can just take a picture and -- sometimes they just -- whatever settings in the camera are, it comes out it with perfect white balance, and sometimes I have to -- it depends, I don't remember.

Q. Okay. So as we sit here today, you're not able to tell me for the Carlino photographs whether you adjusted the image?

A. Yes, I mean there will be more adjustments in the label, there will be labels. But sometimes I have to adjust the top image, the image without the labels. All depends how the image is obtained, the settings.

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Q. And when you adjust the white balance, what does that do to the image? I'm not a photographer, so I don't --

A. As I said, my goal is to make it as close as possible to what I see in the microscope. Because when the camera takes -- or any software takes a picture, if the white balance is off, or if it decides to set white balance in the wrong area, it's out of color.

But you can judge. See, even now, this is kind of bluish-greenish, the background. It's not gray-gray, so there is more blue and green color in the background. Because technically it should be white.

But also it depends on the bulb, if it's taken by the camera it depends on color of the light of the bulb. So there are filters in the microscope. Sometimes filters push; sometimes it's not. But when you push the filter, the intensity of the light drops, the filters are sometimes neutral, sometimes blue. So most of the microscopes have blue filters to compensate for the light.

So there are multiple things which can

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change the color of light. When the camera takes it, I take -- when I take picture, I mean -- then I open it in the computer, so then I can see if the background is white or not. So then I use it as a white.

Q. Okay. So to make sure I understand the process, you take the picture, then you put it on the computer. Then when you see it on the computer, you decide whether you need to adjust it further?

A. Yeah. If I see something wrong, then I adjust it.

Q. Then in addition to the original adjustment to the top picture, then there is also a second adjustment that you -- you're not making, that just the software is making on the bottom photograph here?

A. Could be me. Because see, now I see that there were black and red. See, I put some in black and some in red. So I could have made it all black initially, and then I saw that it's confusing, and then I tried to change color of this and somewhere in the way, red color became more intense; I don't remember now.

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Q. Okay. And so for example, the fact that the picture on the bottom of SC-1 is a different red than the picture on the top of the SC-1, that could be something that you would have adjusted while you were preparing that picture?

A. Something happens during labeling, that's what I can tell you.

Q. And again, I think I asked this. I just want to make sure I understand this.

On the SC-1 through 18, is there any way that I can look at the description of the picture and know whether it has been adjusted or enhanced?

A. They had to be adjusted, most of them, at least the white balance, as I said. That's the basics of processing images. You have to make sure that they at least white balance is correct.

The cropping, turning them, I mean they all come in different angles, I mean, when they are microscopic slides. So there is a degree of adjustment on all images, and it's unavoidable.

Q. All right. And the color enhancement that is evident on the bottom slide of

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SC-1, is there any way to know whether that's occurred in any of the other photographs?

A. I don't know, but I can say that least adjustments are done, or least changes are done to the top images.

Q. Okay. So the top images may be adjusted some, but the bottom images will be adjusted more?

A. Yes, that's the general principle.

Q. On SC-1 you have labeled "inflammation" and then you have labeled "normal tissue"?

A. Yes, a very thin ring of normal tissue.

Q. And how far is the normal tissue on SC-1 from the mesh?

A. I don't think I understand the question.

Q. Well, how far is it? What's the distance between the mesh and the normal tissue on SC-1? An estimate.

A. Which part of the mesh? The most out sort of -- fractions of a millimeter in some places. And in some places, I would say more

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than -- close to a millimeter. It depends.
I mean, sometimes I can see the scar plate extends up to three millimeters beyond the mesh.
Q. Okay. That doesn't occur on SC-1, does it? It doesn't extend?
A. No. In some places it's thin; some places it's thicker. Some places the normal tissue is inside the pore. That's why I do the percentage.
Q. And so what is the -- pick a spot. Here, the middle mesh particle, right there. If you wouldn't mind just circling that one.
A. Which one?
Q. The middle one.
A. This one?
Q. Yeah. How far is the normal tissue from that piece of mesh, approximately?
A. .1-millimeter.
Q. So would that be 100 microns?
A. About a hundred microns.
Q. Okay, thank you.
Let's turn to SC-2. Same question. What are you going to say about it at trial?

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A. Again, this is fibrous bridging, smooth muscle, which is outside of fibrous scar plate. It just demonstrates where scar plate stops and where normal tissue begins.
Q. If I ask you to orient this photograph to the patient, would you be able to do that? Would you be able to tell us where in the patient this slide comes from?
A. No.
Q. If I were to ask you where in this specimen this slide comes from, would you be able to do that?
A. No. Again, I can try to match the pattern most likely to the -- difficult to do.
Yeah. I mean, it's difficult to do.
Q. All right. So for this slide in SC-2, you would not be able to tell us what part of the specimen it came from?
A. No.
Q. How did the pathological finding which you are making regarding this slide, how did that impact Ms. Carlino?
A. It shows fibrous encapsulation, so it's different from mesh by scar, encasement of the

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mesh fibers.
Q. Any other way in which that would impact Ms. Carlino?
A. Another thing here, because scar plate encases the entire structure, so whatever is outside of the mesh, like mucosa. So the blood supply would have to go either around the mesh or through this fibrous bridging. So There's no other way, it's either through it or around it.
That's another implication for scar plate, because it's an obstacle for blood supply.
Q. Any other way in which this would impact Ms. Carlino?
A. No. Stiffness and obstruction of normal blood supply.
Q. And --
A. Contraction as well. So this would be more of a demonstration that there's scar continuously thin, so when it contracts, it contracts the entire sling. That's another --
Q. And what was the degree of contraction in SC-2?
A. I don't know.
Q. Now kind of the same question I

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asked you about SC-1, if you can just circle the middle pore.
A. So you want me to circle a pore or fibers?
Q. Well, I said that poorly. And I was asking about fibers, and thank you for that correction.
The middle fiber.
A. (Witness complies).
Q. So let's just take a second and talk about that so the record is clear.
The fiber is not actually present?
A. Some of it probably is there, you just cannot see it because it's clear.
Q. Okay. And can you tell whether it's there or not?
A. Only if it's a blue fiber. When it's clear, I would need a polarizer to see if it's there.
Q. In this particular one, you didn't look at this photograph to see if it was polarized or not?
A. I don't understand your question.
I mean, if I could look at it if it was

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polarized light? It didn't...
Q. Well, I'm -- I think you think I'm asking you more than I am. I know that you have slides in here that you looked at under polarized light. SC-2, you didn't look at under polarized light; at least not in this photograph?
A. No. But it's not polarized light to take pictures. That's straightforward light microscopy.
Q. That's all I'm trying to establish here. And as you look at that picture, can you tell whether the fiber did or didn't remain in the slide?
A. It wasn't my purpose.
Q. And again, I'm not -- again, I think maybe I'm just not doing a very good job with the question. Let me try it again.
Sometimes the fiber gets removed from the slide because of the cutting process; doesn't it?
A. That's correct.
Q. Okay. And that's just as the microtome slices it, sometimes it will drag the fiber out of the --

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A. Most of it is not dragged by microtome. I think microtome does good job, it cuts with -- it gets detached during processing. Because non-degraded polypropylene is solid material, and it doesn't have any porosity to stick to the slide. Therefore, its adherence is very loose.
The only thing which is holding it, is the degradation layer, which is porous and it's stuck to the tissue. So if that bond is not strong enough, it just curls up and it floats away.
Q. Okay. And so, for example, the top of the diagram in SC-2 the mesh fiber might be there, it might not be there?
A. May or may not, yes.
Q. If it's not there, I mean, you can tell from looking, that mesh fiber used to be there?
A. Yes, I certainly know it was there.
Q. Sure. And again, I'm just trying to make the record clear on this.
And so either it's not visible on the slide, or it's been removed in the cutting process?

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A. It's either not visible or it became detached during processing.
Q. Okay. So then same question regarding the fiber there. How close is the normal tissue to that fiber?
A. Within 100 microns, I mean, the closest. If we're talking about average, for median, or minimum --
(Reporter sought clarification).
A. Average, median or minimum, or maximum. And that specific fiber in the middle, it's less than 100 microns.
Q. All right.
A. But some areas I can see from here, probably going up to 3, 4 hundred microns, or even a millimeter.
Q. And is this photograph on the bottom of SC-2, is the color adjusted on that photograph?
A. As I said, I mean, all of the images would have to be adjusted to a degree. How much of an adjustment was it, there are many factors.
I try to make them more uniform, so

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they have the same intensity of color, same contrast, so they look more or less the same.
Q. And this stain that you used for SC-2, that's an actin stain to show the smooth muscle?
A. Yes.
Q. And I think this is self-evident, but I just don't remember if I asked you about this on the SC-1.
The bottom slide where the yellow is drawn in, that's something you've drawn in on the computer to show where the mesh fiber was?
A. Yes.
Q. Okay. Earlier, when you were discussing SC-2, you talked about blood supply, and there had been no blood supply to the tissue surrounding the mesh. Is that tissue innervated?
A. Which tissue? Which is outside?
Q. The tissue that is shown on SC-2; is that tissue innervated?
A. Yeah, I did the S100 stain, so -- and I think a neurofilament stain.
Q. Dr. Iakovlev, let's talk a little about SC-3. What are you going to tell the jury

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about that slide?
A. This part clearly showed two parts of the mesh, which were sectioned in one section.
So if it was a flat permutation, it's either flat sectioning along the surface, and then we would get the pattern of the mesh crossing squares.
But in this case, there are two planes on the mesh. So the mesh curled and twisted to produce this type of orientation in one section.
Q. Can you tell us from what part of the body the specimen that's depicted on SC-3 came from?
A. What do you mean "part of the body"?
Q. Can you orient it in the body?
A. It's suburethral, somewhere of urethral.
Q. Could you orient it? If I gave you a diagram, could you show us where it was?
A. Not specifically. I can show the area where it was, but to get perfect orientation would be impossible to restore.
Q. And can you tell us where in the

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specimen this came from?
A. What do you mean?
Q. Like, for example, could you draw a diagram of the specimen and show us what part of this specimen is depicted in SC-3?
A. Well, I didn't have a diagram. I received just a slide. So if I had a diagram, I could try to find the twisted spot.
Q. But you don't have a photograph or diagram in this case?
A. No.
Q. So because of that, you can't orient this and show us what part of the specimen it's from?
A. That is correct.
Q. Now, could you explain to me again your testimony regarding the different planes; and I apologize, I don't understand it. So, how is it that you say the different planes show that there's curling?
A. So if we have a flat object; mesh is flat when it's manufactured. So there are two ways of sectioning it. Either it's parallel, and then you get the pattern on the mesh with squares.

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Or, either perpendicular or angled, but in any case, it is a cross-section through the plane.
So you will have -- if it is flat, you will have just one plane of the mesh. Like we saw in picture number one. So, flat, one section.
Now, to produce two layers of mesh in the same section, you have to have second layer. And I assume it was just one device.
There is no indication that there were two meshes inserted. So it's the same mesh which folded or curled, and the other portion was also curved this way.
So one is straight, one is curved. So the orientation is somewhat similar to this. That's the only way, geometrically, to produce that figure in one section.
Q. Now, you cannot say whether that occurred during implantation or occurred postimplantation, can you?
A. No. It occurred somewhere in the body. Scar tissue immobilized that shape, which is growing around it, and it became fixed. When it occurred? I know that it occurred before

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explantation, that's as far as I can say.
Q. Okay. But you can't tell us whether it occurred at the time of placement or whether it occurred postplacement?
A. No. My understanding is, I mean, they tried to make it flat and they checked it intraoperatively so...
Q. What is your opinion regarding why you know that this happened in vivo and did not happen post-explantation?
A. All spaces are filled with scar tissue. Scar tissue can grow when only when it is in vivo.
This whole area, here in between -- do you want me to mark it? This is all filled by scar tissue (indicates). And it's the only the body which can produce scar tissue.
Q. Okay. And I guess my question is more, how do you know that the curling of the mesh occurred in vivo, as opposed to curling of the specimen post explantation?
A. I just told you. There is scar tissue in that shape between the mesh fibers. The only way to produce scar tissue is to have that

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shape in the body while scar tissue forms around it.

Q. And scar tissue does not deform post-explantation?

A. What do you mean deform? It's not deformation. It's the location between the fibers.

Q. And that -- and it's your --

A. It cannot be grown between the fibers outside of the body.

Q. And it's your opinion that that shape cannot change post-explantation?

A. Shape of mesh, or shape of scar tissue?

Q. Shape of scar tissue?

A. We're not talking about shape. We're talking about the location of scar tissue. Location of scar tissue is between mesh fibers. Shape can change, but the location cannot change.

Q. Okay. And it's your testimony that that location cannot change post-explantation?

A. That's impossible. That's a process in vivo.

Q. And you agree with me that vaginal tissue does shrink post-explantation?

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A. Yes.

Q. You agree that vaginal tissue has a different elasticity?

A. What do you mean?

Q. Is vaginal tissue elastic?

A. Normal?

Q. Yes.

A. Yes.

Q. And when a piece of tissue is excised from the vagina, does it contract?

A. Depends what tissue. If it is softer tissue, it can contract. If there is muscle, it can contract. If it's scar tissue, firm, just pure collagen, it wouldn't contract much.

Q. Dr. Iakovlev, did any of Ms. Carlino's treating physicians reach the conclusion that her mesh curled?

A. Might be something described in the operative report. Sometimes they describe it, sometimes they don't. I mean, it depends. All depends on detail -- how much detail they put in their operative report.

Sometimes I get quite curled meshes in

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the report, let's see. This is implantation. I have to see the explant record.

EXHIBIT NO. 10: Operative Report dated December 17, 2010, by Ellen Conner, M.D., Bates No. CARLINOS_JSUMC_MDR00151 - MDR00152.

BY MR. COMBS:

Q. And, Doctor, I've handed you Dr. Conner's operative report from the December 17, 2010 explantation. And Dr. Conner did not make the finding that Ms. Carlino's mesh had curled in vivo, did she?

A. Doesn't say either way what's flat or curled, doesn't describe mesh much. Describes maybe what was done, rather than the state of the mesh.

Q. There's no finding in Dr. Conner's report that the mesh is curled, is there?

A. There's no description of the mesh.

Q. And you haven't reviewed Dr. Conner's deposition, have you?

A. No.

Q. On the photographs on SC-3, again,

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the color is changed between the top and the bottom slides. Is that part of the process that you told us about earlier with the Photoshop program?

A. I'm not sure if there is any change in color; it looks the same to me.

Q. Okay. So is it your belief that the color is the same on these slides?

A. Yeah, I mean, see, depending on printer, also. I can see this is more yellow, this is greenish, all these colors are different. And it also depends on Word, when it gets embedded in Word. Word does something to images, I have no idea.

Q. All right. So the use of the program Word can also be something that can affect the --

A. See, the thing is that I'm not relying on any color, it's illustrations. I don't know why we're so hooked on the colors.

Q. Okay. Dr. Iakovlev, the food is here. Do we want to take a break?

-- RECESS AT 12:35 --

-- UPON RESUMING AT 1:14 --

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BY MR. COMBS:
Q. Okay. Dr. Iakovlev, are you ready to go?
A. Yes.
Q. Thank you. So when we took the break, I had asked you about SC-3 and now I'm going to ask you about SC-4 and SC-5.
It's my understanding from the narrative in your report, you were using those slides to demonstrate foreign body reaction to the jury?
A. That's correct.
Q. So what is it you're going to use these two slides to tell the jury?
A. That there is foreign body reactions surrounding the mesh fibers. And then there is scar plate on the outside of the foreign body reaction.
Q. And is this foreign body reaction mild, moderate, intense?
A. For that specific, I would say it's pretty intense, and that's pretty much as high as it goes. And I'm judging it, because I've seen 300 specimens.

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Q. And what is your criteria that you use to scale the foreign body response?
A. I use -- well, the number of foreign body type cells or micro fibers. I mean, either it's one layer in occasional fibers, or they become multilayered, and there are several cells. When this halo or foreign body reaction is several cells thick. And it then becomes confluent, like that multilayering is pretty much encircling most of the fibers. As you can see here, that this area is confluent, and this area is confluent (indicating).
Q. Dr. Iakovlev, I'm sorry to interrupt you.
-- OFF THE RECORD DISCUSSION --
BY MR. COMBS:
Q. Okay. Dr. Iakovlev, can you mark in green what you're talking to us about, about the confluent layer?
A. So I outline the macrophages -- I can outline them here. As you can see, these are larger areas; in comparison with this one, it would be smaller areas here. So there would be more confluency in the SC-4 rather than SC-5.

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So what I use as a criterion, as I said, number of cells, multilayering, confluency, and the extent when this confluency stretches along the mesh.
So if a segment of the mesh within the 4X objective has this confluent foreign body type reaction, it would be a grade four.
If there are some gaps, some fibers do not fully classify, qualify for confluent, then it would be grade three.
And then if I have only occasional patches of this confluent or multilayered -- not confluent, multilayer, it would be grade two.
Very occasional macrophages, grade one. And no macrophages at all would be grade zero. That's pretty much it.
Q. So is it a continuum from zero to four?
A. Yes.
Q. Four is the highest, zero the lowest?
A. Yes.
Q. And how did you grade this?
A. This would be grade four.
But again, see, I would have to have a

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microscopic field of 4X subjective; this is much smaller.
So if we would assume that this extends further up to here (indicating), and it has the same appearance, this would be grade four.
Q. All right. And so the record is clear, what you're showing us with your hands is that the top picture on SC-4, that if there was confluent en circulation on additional pieces of mesh -- okay. So we've turned now back to SC-1?
A. So SC-1, you can see that there is confluency, at least from this moment, somewhere in here. So this would be grade four (indicating).
Q. And you marked that with a green magic marker?
A. Yes. Assuming if we check this area, this gap (indicating) - I'll mark it with parallel lines - there is not as much foreign body reaction.
But I've marked foreign body reaction by the worst area. So the grading is selected by the worst, by the most inflamed area. Because this would be more important.
Q. Is there any written criteria that

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you're referring to in this grading of foreign body reaction?

A. I think it was in one abstract somewhere -- maybe not, I don't know. I'm using it for future analysis. I don't think paper, full paper -- no. Full paper was not written or published using this type of analysis.

Q. Is this your own analysis or is this to reference someone else?

A. No, the grading was designed by me.

Q. Okay.

A. After I've seen 200 specimens and so forth, then I could analyze what's happening, and I had a full spectrum of what is the lowest and what is the highest.

I picked the worst ones, and this would be grade four. I picked the intermediate ones, and then I tried to decide what would be more reliable reproducible criteria, and then I came up with this system.

Q. Okay. As of today, the system is not published anywhere?

A. No.

Q. And if you could -- I don't want

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to retread this testimony at all, but if you can quickly tell us, to make sure that I understand.

Zero is no microphages?

A. Yeah, but I'm not sure while we're talking about this. This is not directly relevant to my opinions. My opinions are based on if there is or there is not foreign body reaction.

So when I do the grading, this is for future analysis. I mean, I can tell you that this is intense, but the precise sort of grading and criteria and everything else, I mean, this doesn't affect my opinions.

Q. Okay. For Ms. Carlino, that's grade four?

A. I would grade it as grade four. You can check this in my pathology report if it was a grade four.

Q. I think it's on the very back of that?

A. Yes, it was grade four.

Q. Okay. And could you just briefly again tell us the definition of grade four. I just want to make sure it's clear on the record.

A. To me, grade four, as I said, was

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the highest possible foreign body response. So when I reached the point when I had enough specimens to feel that I had a whole spectrum of foreign body reaction, I take the worst ones and analyzed what is common between them.

I realized that there is confluency, and then I picked the times four objective as a criterion to see the confluency of foreign body reaction. Because if I switched to ten, then I would find some gaps all the time.

Q. Okay. So let's look at the bottom picture. And in it you have culled out on SC-4, normal tissue.

So we don't get our colors confused, how far is the normal tissue from the mesh fiber in SC-4?

A. Minimum, medium, maximum?

Q. Like, for example, there (indicating). How far is that?

A. This was the minimum.

Q. How far is that?

A. This is the smallest. This would probably be 40 microns.

Q. Could you circle that?

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A. (Witness complies).

Q. And you circled that in red. And that would be approximately 40 microns?

A. Yes.

Q. And for example here, where you have "scar"?

A. Here, it would be much thicker, 200 microns, somewhere in that range, 300.

Q. Could you just, for the one that's 40 microns, just put an "A". And for the one that's 300, just put "B". Just so the record is clear.

A. (Witness complies).

Q. Thank you.

Is the area that you've marked with "B", is that larger or smaller than the diameter of the mesh fiber that's depicted on SC-4?

A. It's about the same diameter, so we can use it. I mean, the diameter should be about 150. So I guess that would be 150. Yes, I could use that as a measurement.

Q. Okay. So after comparing the area circled in B with the mesh fiber, your estimate would be, it would be approximately 150 --

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A. Probably closer to 200, because tissue retracts somewhat. So this space is a little bit larger. So you can even see, this is the fiber here. So this is 150, roughly, for TVT.

So you can see that there is a direction about 20 percent, 25 percent; so it would be 170-something.

Yes, this would be closer to 200, just over 200 microns.

Q. And when you say "closer to 200", you're referring to the one you circled at B?

A. Yes.

Q. Thank you.

Dr. Iakovlev, I want to ask you now about slides SC-6 through 11. Are those ones that collectively you are using to discuss the nerves in Ms. Carlino's specimen?

A. Yes. This is the images of the innervation in the specimen.

Q. Now, in Ms. Carlino's case, you did not rely on the opinion of a neuropathologist, did you?

A. No.

Q. Did you count the nerve density

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for Ms. Carlino?

A. We can check. Yes, I did.

Q. And what was your finding on the nerve density?

A. Entire issue .982. Within mesh pores, and in this case mostly pores, .4. And outside of the mesh, 1.29.

Q. I couldn't hear the last thing you said?

A. 1.29.

Q. So is it your opinion that Ms. Carlino's nerve density is abnormal?

A. There's no such thing as normal or abnormal. I mean, nerve density, as I said, I mean, I'm collecting as future analysis. It has nothing to do with my opinions.

My opinions are based on the presence or absence of the nerves. I don't think we need to discuss density at all.

Q. All right. Your calculation of Ms. Carlino's nerve density does not play a role in your opinion in this case?

A. No.

Q. Did you make any finding in your

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report that any of Ms. Carlino's nerves are abnormal?

A. It's hard to say. It was little bit dried and cauterized. So the tissue wasn't really in a perfectly crisp state. So it would be very difficult to assess morphology of the nerves due to artifacts; drying and cautery.

Q. At the trial of this case, you do not plan to tell the jury that any of Ms. Carlino's nerves were at fault; do you?

A. No. I have no reason to believe that they were abnormal.

Q. Okay. And no finding, that, for example, Ms. Carlino had any traumatic neuromas depicted in any of the slides?

A. No, I didn't detect that.

Q. No findings that Ms. Carlino had an entrapped nerve?

A. Well, they are entrapped. They are in the scar tissue. So by location within the scar, they're entrapped in the scar.

Q. Did you make any finding that Ms. Carlino had nerves that you believed were entrapped within pores of mesh?

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A. Yes. In fact, there were two branches which I assessed are present within the nerve pores.

Q. Which slides are those?

A. I took them, and which slides --

Q. I didn't ask that.

A. I don't remember, because these slides, some of them are so high magnification I don't know if it was in the pore or outside.

Q. Okay. So what would your testimony to the jury be on that point of whether any nerves were entrapped within Ms. Carlino's mesh?

A. All of this shows -- most of the shown nerve fibers are within the scar tissue. They are entrapped in scar tissue.

If it's outside or inside, it doesn't really matter. Because one section can be inside the pore and then outside of the pore; it makes no difference.

It's in the scar tissue surrounded by the mesh, the whole mesh scar plate is one solid structure.

Q. Just to make sure that I

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understand. Your testimony will be that's it's within the scar tissue, but you cannot say whether it is or is not within the mesh pore?

A. Two of them were assessed as within mesh pore.

I mean, if you just think about this one -- just look at SC-7. So the mesh extends somewhere from here to there. So partially, this nerve branch is within the space within the mesh.

This is kind of on the line, so this would be more difficult. But in this image, I don't know what's on this side, if I counted these specific nerve branches inside, I don't know. Again, it makes little difference.

It only makes a difference when there's a traumatic neuroma right inside. Scar tissue is innervated, that's the main thing.

Q. And you made no finding in this case that Ms. Carlino had mesh filaments within the nerve ganglia, did you?

A. I don't think I had ganglia. No. There are no ganglia.

Q. And do you agree that a pathologist cannot look at a nerve on a

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histopathological slide and know whether it is causing pain?

A. Say it again. Cannot look at what?

Q. Do you agree that a pathologist cannot look at a nerve on a histopathological slide, and know whether it is causing pain?

A. Well, pain is a transient sensation. So this would be -- so there is something abnormal; pathologists can describe what is abnormal, if this can cause pain. And then when you correlate it with clinical symptoms, and then you correlate it with pathology, this becomes a conclusion.

Q. Based on the slide itself, you cannot make that finding?

A. Well, I can say what's abnormal in the slide.

Q. Okay.

A. Scarring is abnormal, presence of foreign body is abnormal, innervation within the scar is abnormal, because there are branches that are trapped in the scar.

Now, this was removed for pain, for

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dyspareunia. And the only abnormality I see, scar tissue with foreign body, and it is innervated. Putting these pieces together, this is the lesion and this caused the pain.

Q. Now, do you know that from looking at the slide? If somebody presented you with a slide and you had no clinical history, would you be able to look at it and say whether that person was or was not in pain?

A. When I look at the slide, I see scar tissue and nerve branches within scar tissue.

I would say, this tissue is at risk for pain; without any history. Because it's abnormal tissue, it's scar, and nerves are present in abnormal environment. So without any history, I would say that this tissue is at risk for pain already.

If I have a history of pain, I say "well, here I go, that's the cause of pain".

Q. Okay. Without a history, you cannot look at it and tell whether the person is or is not in pain, can you?

A. Without the history, if I look at this slide, I would say, there is reasonable degree

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of probability that this was painful. That's what I would say.

Q. Is there any clinical literature that you can point me to that makes that correlation for pelvic pain?

A. For pelvic pain?

Q. Yes.

A. There was at least one case report when the pain was there, the sling was excised and there was traumatic neuroma, or the nerve was deformed.

(Reporter sought clarification).

The nerve was deformed. One for sure, that was certainly for transvaginal. That one I remember for sure.

Yeah, at least one paper for transvaginal sling. And the pain was caused by neuroma, or nerve deformation caused by the mesh.

Q. And there is no nerve deformation or neuroma in Ms. Carlino's case, is there?

A. There are nerves in there, in the spaces.

Q. Okay. But you detected no neuromas in Ms. Carlino's case, did you?

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A. No. I detected just nerves.
Q. Dr. Iakovlev, I want to ask you one follow up question on that.
The case report that you mentioned, do you remember who published that?
A. No, I don't remember. I said that.
Q. Do you know at what point it was published?
A. Quite a number of years ago, at least four or five years ago. I think four years.
Q. Any other literature that you're relying on for that opinion other than that one case report?
A. Kosterhaliften mentioned that in his collection of hernia specimens, at least 60 percent of those hernias which were removed for pain, contained nerve abnormalities, nerve involvement. That was for hernia.
And then we published paper just recently -- or had some abstracts in the paper where we published, when we compared hernia specimens removed for recurrence and compared nerve density with those which were removed for pain, and

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nerve density was much higher. Of course we had some neuromas, but not all of them had neuromas, just higher in their density.
(Reporter sought clarification).
A. Some of them just had pain and high nerve density.
Q. Dr. Iakovlev, what are the various types of nerve receptors?
A. Well, either we're talking about pain receptors, and then we're talking about other receptors, like temperature, touch, vibration.
Q. What are the pain receptors?
A. Pain receptors are usually just bare endings of the nerves.
Q. And what are they called?
A. Nociceptors.
Q. And what is the prevalence of nociceptors in the interior vaginal wall?
A. What do you mean "prevalence"?
Q. What is the prevalence?
A. What's the density?
Q. Okay. What is the density?
A. I don't know. It's there. I mean, that's why we can sense -- I think we're

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drifting again into general questions.
Q. What magnification does it take to detect a nociceptor?
A. You need a stain to detect.
But we are drifting into general questions again. We won't have time to do the second case.
Q. What stain do you need?
A. You can try PGP 9.5, I believe.
Q. And what magnification do you need?
A. Might be quite high, up to 100.
Q. And none of Ms. Carlino's slides are stained with PGP 9.5, are they?
A. No. I don't need it. Why do you need that?
Q. Okay. My question is: Were any of them stained with PGP 9.5? And the answer is "no", correct?
A. That is correct.
Q. Now is the innervation of scar tissue a normal or abnormal finding?
A. That's a general question.
Q. In Ms. Carlino's case, is it a

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normal or abnormal finding that you have found that Ms. Carlino's mesh is innervated -- strike that -- that the scar is innervated in Ms. Carlino; is that normal or abnormal?
A. It's abnormal. Scar tissue is abnormal anywhere. So any other changes within the scar tissue are abnormal, because the environment is abnormal to begin with.
Q. Is it a normal or abnormal finding -- ignoring that the scar tissue is abnormal -- is it normal or abnormal that her scar tissue is innervated?
A. I think you're mixing terms.
Is it normal to die from heart attack? Yes, it is, because people do die. Can we use "normal" in that terminology? No.
I think we need to separate normal, as normal tissue without any changes. Or tissue changes which are expected as a response to something. So let's separate.
Normal, normal tissue, no changes. If there's any change, then we will use the term "as expected".
Q. Okay. Is the innervation of the

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scar tissue with Ms. Carlino, is that expected?
A. It is expected. It could have been expected even before the meshes were put on the market.
Q. And that would be true of any scar tissue, wouldn't it?
A. Yes. Some of them get innervated; some of them don't. Some of them get more dense innervation, some of them are less dense.
Q. All right. So let's talk about SC-6. You stained that with S100?
A. Yes.
Q. Why did you stain it with S100?
A. Wait a second. Some of them were stained with neurofilament.
Q. SC-6, it says "S100". I'm not trying to trick you.
A. Yes, it was S100.
Q. Was the point of that to show the nerve tissue?
A. Yes. It's the most robust stain. The PGP 9.5 doesn't work well, either. I tried different stains, and my conclusion was that S100 is the best, most robust stain for the purpose I am

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doing. So that was my conclusion.
Q. Now, let's talk about SC-6. What is it that you're going to tell the jury about SC-6?
A. There are nerves in the tissue surrounding the mesh.
Q. And as it says in the little legend, that's where the black arrows are pointing?
A. Yes. It helps to identify the nerve branches.
Q. Okay. Where was this piece of tissue in Ms. Carlino's body?
A. Somewhere around the mesh.
Q. Would you be able to orient it for us?
A. No.
Q. Where is the slide taken from the specimen?
A. What do you, "where is the slide"?
Q. Yeah, if we had a diagram, would you be able to draw where this specimen is from?
A. If I have a slide, and I can find it in the microscope then I could draw it for you.
Q. In this case you have no diagram or picture, right?

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A. No. You have the slide, I sent it to you.
Q. I understand. But you don't have a diagram of the specimen?
A. No, I don't understand why --
Q. You don't have a photograph of the specimen?
A. No. Why do we need it?
Q. So my question is, can you tell us what part of the specimen this slide comes from, SC-6?
A. No.
Q. Where is the mesh located in SC-6?
A. Probably just below, somewhere here.
Q. Would you agree with me that SC-6 does not depict any mesh fibers?
A. That's correct.
Q. Doesn't depict any mesh pores either, does it?
A. Not sure about the pores. Pores are space which is filled with scar tissue, it cannot represent part of the pore.
Depending on mesh fiber location, if they are located diagonally, like in corners, then

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part of this image would be in the pore. Again, I don't know.
Q. And would you agree with me that what is depicted on SC-6 are nerve twigs?
A. See, it's a sliding scale, what you call a twig, what you call a branch, what you call a neurofiber or nerve.
Usually, usually to call it the nerve, you need perineurium. Anything smaller than that, it doesn't have defined perineurium, then it becomes a nerve twig.
Anything which contains only one single nerve fiber would become a nerve fiber.
Q. All right. Do you describe what you have pointed out in SC-6 as a nerve twig?
A. This larger one could be classified as a nerve. The other one could be -- I mean, it's hard to say. The tissue was a little bit compromised, and it didn't work well. So it was a little bit changed, altered.
The smallest one would probably be nerve twig. The larger ones could be nerve twigs, could be nerve, like nerves. I mean, again, there is no difference. It's all just thickness of them,

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how many nerve fibers are within that bundle.
Q. Dr. Iakovlev, do you see on here there are some white bands that are running parallel to the slide?
A. Yes.
Q. So, for example --
A. Uhm-hmm.
Q. That (indicating).
A. Yes.
Q. What are those?
A. This is retraction, when tissue retracts during processing. So then there is space in between them.
Q. And what about that? Why don't you circle that; what is that?
A. So this looks like a small vessel, and this as well (indicating), from this power, what I see. But then just below that, it's retraction.
Q. Okay. So what you've circled on SC-6 would be things that looked to you like blood vessels?
A. Yes. Most likely blood vessels, not lymphatics.

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Q. And those would be within what you have described as a scar plate?
A. Yes.
Q. The nerve fibers that you've identified on SC-6, are those coming from a peripheral nerve?
A. What do you mean? They're all peripheral nerves. You mean autonomous or --
Are you asking about peripheral nerve system versus autonomous?
Q. Yes.
A. That's difficult question. Because some of the parts of the autonomous nerve system are myelinated, so they will be stained by some kind of stain.
In any case, autonomous or nonautonomous, they are combination of motor and sensory, both.
Q. You don't know whether that is a peripheral or autonomic nerve, do you?
A. As I said, some of them could be either.
Q. But you can't --
A. No, I cannot separate them, no,

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that's true. But autonomous nervous system also conduct pain, otherwise, you wouldn't feel pain in the internal organs. So it doesn't matter what type of neuro system they coming from, they can deliver pain sensation; that's the main reason.
Q. What nerve are these fibers branching from?
A. That would be impossible to trace. I mean, they are just small branches.
Q. And you do not know what nerve they --
A. They don't have names. They are so small, they don't have any names.
Q. And do you know what nerve they ultimately branch from?
A. No.
Q. For any of the nerves that are set forth on SC-6 through SC-11, you cannot tell us whether that is a sensory nerve, can you?
A. I can tell you one thing. It doesn't matter what nervous system they coming from, what nerves they coming from. Some of them will be delivering sensation; it's unavoidable.
Q. So here is my question: For the

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nerves that are depicted from SC-6 to SC-11, you cannot tell us whether any of those are sensory nerves, can you?
A. There is no such a thing as -- well, there may be some purely sensory nerves, yes. Most of the peripheral nerves will be mixed in autonomous nervous system, it all depends.
(Reporter sought clarification).
A. Some of the peripheral nerves are sensory; most of the peripheral nerves will be mixed. Some of the autonomous nerves will be sensory and motor, it all depends pre-ganglionic or post-ganglionic.
But the main piece of information we need to know, that at least some of them will contain some of the sensory fibers.
Q. For any of the nerves that are depicted on SC-6 through SC-11, you cannot tell us whether that is a sensory nerve, can you?
A. I just answered you. The main piece of information that some of them will contain at least some sensory fibers within the nerves.
You separating nerves, we have to think about fibers, not nerves. Nerve is a combination

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of fibers, signals are going through the fibers, each fiber can deliver a different signal.

Q. Okay. I'm pointing at this nerve, far left on SC-6. You can't tell whether that's a sensory nerve, can you?

A. Let's talk about fibers not --

Q. Dr. Iakovlev, please answer my question.

A. Peripheral nerves are almost all mixed motor and sensory. You're trying to separate something which doesn't exist -- it does exist, but it's very small proportion, just purely sensory.

I can tell you if it is peripheral nerve, it's not autonomous, 100 percent it will have some sensory fibers. If it's autonomous, then it depends on the nerve. Some of them will have sensory fibers, some of them will not.

Q. And the nerve I just pointed to, far left on SC-6, you cannot tell us whether that is or is not a sensory nerve?

A. So based on the classification --

Q. Can you answer my question first? Then you can say whatever you want.

A. Statistically --

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MR. ZIMMERMAN: He has to clarify your question.

BY MR. COMBS:

Q. The first question is: Can you tell us whether that is or isn't a sensory nerve?

A. I can tell you with a reasonable degree of medically certainty, statistically, there will be sensory fibers in that nerve.

Q. So you haven't answered my question. Can you tell me whether that nerve, far left, SC-6, is a sensory nerve?

A. If we talk about peripheral nerve system, there will be very small proportion purely sensory nerves. You're trying to pick less than 5 percent out of all peripheral systems and ask me that question. I think it's not valid question.

If we talk about from what we know and statistically how many nerves, and how the separation of motor and sensory fibers within the nervous systems is, that statistically there is higher probability that at least some of these fibers in that nerve will be sensory is higher than there is no sensory fibers at all.

Q. Okay. Now, I had asked you to

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directly answer this --

MR. COMBS: He can explain all he wants after this.

MR. ZIMMERMAN: You get to ask the question you want, but he has to give the answer that he has to give.

BY MR. COMBS:

Q. Okay. And so are you refusing to give me a "yes" or "no" answer to that question?

A. Yeah, I cannot answer "yes" or "no". It's impossible.

The way you question, and the way you ask the question, it's impossible to answer "yes" or "no".

Q. So you're unable to say, yes, that's a sensory nerve?

A. If I say "yes" or "no" answering your question, it will not be a true answer. It will not reflect --

Q. It cuts both ways. You can't say it is, you can't say it isn't?

A. I can say there is more probability that there are sensory fibers in there than no, much more.

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Q. And is the magnification that is used for SC-6, sufficient to detect a nerve receptor?

A. I'm not looking for nerve receptors. All nerves end up --

Q. Dr. Iakovlev, again, just answer my question.

MR. ZIMMERMAN: He's trying to answer the question. Let him finish the answer.

BY MR. COMBS:

Q. I apologize for interrupting you. Do you want me to repose the question?

A. I mean, why are you asking about receptors if I was not looking for them?

Q. Okay. Well, I get to ask the questions here. I get to ask the questions I want to ask you.

And here is my question: Is the power that you used for SC-6, which is ten times, is that sufficient to detect nerve receptors?

A. If it was a different stain, with a good eye, it would be bordering on sufficient, just bordering it. It wouldn't be obvious, but you can see some structures in that magnification.

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You would need to actually study the nerve receptors with a different stain. You would need to go higher in most cases.

Q. And that's a stain that you didn't use on these slides, you didn't use the PGP 9.5?

A. It wasn't my purpose.

And it's not a great stain either, so...

Q. Okay. Now do we need to go through SC-6 through 11 one by one, or can you tell me collectively what you're going to be telling the jury about these slides?

A. As I said, I've repeated several times. The main features are: There are nerve branches; the tissue is innervated; and they're located in abnormal environment. They are located in scar tissue, and some of them are hidden within the mesh pores. That's abnormal.

Q. And that would be what you're going to tell the jury about for all of the slides, SC-6 through 11?

A. Yes.

Q. If there's something different about a particular one, we'll stop and talk about it.

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A. Yes. And that most of the nerve fibers we see in these nerves are sensors, are more. There are more sensory nerve fibers than motor, so they will be delivering sensations.

Q. Let me ask you a question about SC-7.

A. Yes.

Q. Okay. Top picture of SC-7, do you agree that that nerve is -- do you agree it's very faint?

A. As I said, I mean, tissue was somewhat compromised. Little bit dry, little bit cauterized; so you must stain well in some areas. Some areas were better, some areas were worse.

Q. Just to make sure I understand. When you say "cauterized" that means it was cut -- strike that.

Cauterizing means that the mesh was explanted using heat as a source, and basically the tissue burned off?

A. Yes. Burned on the surface and then gradually deeper. It was more or less cooked, yeah.

Q. Okay. And so that changed the

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integrity of the tissue that you had to look at?

A. In some parts, yes.

Q. And you also said that the tissue was dry. What does that mean?

A. Because during excision when the cauterize is used, some tissue dries up because of the heat. I mean, some tissues just burns, and some tissue dries in some areas.

Q. And as a result of those two factors, the nerves stained more faintly?

A. Some of them, yes.

Q. Did you do any enhancement on this slide? I'm talking now about SC-7?

A. I just circled the nerve, that's all I did. You can barely see it, but I could see better in the microscope.

Q. Dr. Iakovlev, a follow-up question about SC-8.

A. Uhm-hmm.

Q. On SC-8 you've identified a nerve and that's what you pointed to with the arrow circled in brown or black?

A. Yes.

Q. How far is that nerve away from

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the mesh?

A. I don't know. What do you mean "how far"? How far from closest mesh fiber?

Q. Yes, sir.

A. Something like half a millimeter.

Q. So would it be your --

A. It's an estimate. I'm not quite sure. Maybe less, maybe 300 microns, because this seem to be deformed.

So if I want to use the mesh fiber as a scale, it would be difficult because this space is deformed. So this may not be 150. So it might be -- this is difficult. Might be anywhere between 2 to 4 hundred, just because of this distortion.

Q. I understand it's an estimate, but the estimate of the distance between the circled part and the mesh would be somewhere between 200 and 400?

A. Not the mesh, the closest fiber in the picture. I mean, I don't know what's beyond, maybe there's nerve fiber in this, that would probably be close.

Q. Something between the fiber at the bottom of that picture and the mesh, something like

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200 to 400 microns?
A. Probably, yes. That's the best estimate right now.
Q. Now, is there any difference of the character of this tissue I'm pointing at here and this tissue up here (indicating)?
And we can draw on that to make clear for the record what we're talking about. But here the basic question is: Is this type of tissue the same as that tissue (indicating)?
A. It's the same fibrous tissue, it's scar to me.
Q. Okay. So your opinion would be all of the blue tissue that is depicted in SC-8 is scar tissue?
A. Looks like, from this picture, yeah.
Q. Dr. Iakovlev, kind of same question about SC-9. How far are the nerves from that mesh found?
A. This twig is 20 microns, or maybe JUST touching it already. Because of the deformation, it might be sitting right next to the fiber.
Q. And then the one below it?

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A. One below it is a little further, roughly 200 microns.
Q. Now on the slide SC-9, is there any artifact distortion at the top left-hand corner of that picture --
A. Yes.
Q. -- the northwest?
A. Yes, there is. That is why I cannot tell you exact distance.
Q. Just so I understand, what is artifact distortion?
A. Some tissue became slightly displaced during cutting or processing.
Q. So what's depicted on this SC-9, that would not be the way that this would have looked at, if you looked in vivo, because of the cutting process?
A. Yes. And to a degree there is some artifact, yes, that is true. That's why I couldn't tell you exact distance.
Q. Same question on the next one on SC10; how far is that nerve from the mesh?
A. 60 microns, I don't understand the difference. It makes no difference, the distance.

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Q. Okay. And again, same question that I asked you earlier: Is the character of the tissue the same in this section and in that section?
A. It looks the same to me. It's a little bit more frayed, because of the age, kind of more fluffier because it's not supported; but same tissue.
Q. All right. And it's your opinion that that is all scar tissue depicted? All the blue on the bottom that is on SC-10 is scar?
A. Well I mean -- it's coming out from normal tissue. All nerve fibers are branches, they start in normal tissue. Then you can see the direction -- I'm drawing it for you -- you see the direction goes all in the scar tissue (indicating).
So one end is pointing towards normal tissue, the other end is pointing towards scar tissue. All of the nerves originate in normal tissue, they end up in scar tissue.
So depends on where we cut them, sometimes they're closer to normal; sometimes they're deeper inside in scar tissue. It's all relevant.

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We measuring -- you're asking 60 or 70 microns, I can cut three or four sections and it will be instantly 100 or 200.
This is so artificial what you're trying to do, separate into measurements. And it's so artificial, it has no perspective for three dimensionality of the specimen.
Q. And that would be true of all the slides, wouldn't it?
A. Yes, it would be true for all the slides. So measurements in two-dimensional planes or three-dimensional objects are meaningless.
Q. And the line that you've drawn on SC-10, that's your demarcation line between scar tissue and normal tissue?
A. No. This is --
Q. I apologize, I just didn't hear you.
A. This is direction of the nerve position.
Q. Okay.
A. Assuming that the mesh is going this way, the mesh can go like this. So this end may be going, pointing (indicating) -- I mean, we

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are trying to make -- trying to fit the square peg in a round hole.

Q. When you sectioned the block, did you try to trace any of these nerves throughout the entire specimen?

A. No, why? You want to do it? I didn't want to do it. There is no meaning of that.

I can see some of them end up in the scar tissue, some of them end up more normal. I know that all of them come from normal tissue, and that's innervating or crossing the scar.

Q. So you would not have done that for any nerves found within any of the slides from SC-6 through SC-11?

A. No. I mean, it would have no difference to me, to my opinions.

Some of them I see, as I said, deep inside scar tissue. Some of them a little bit outside, some of them are all normal tissue.

When I get larger specimens, I can see a lot of nerves in normal tissue. And sometimes I get perfect sectioning when I can see that it dives from normal tissue into the scar.

Q. I want to ask you now about SC-11.

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What is it you're going to tell the jury about that slide?

A. This is a myeloperoxidase stain. And it shows that the microphages, which are foreign body type reactions, they spill myeloperoxidase. It's one of their peroxidative substances, and the mesh fibers are surrounded by oxidated perineurium.

Q. Now, same question I've asked you a couple of times before. You cannot tell us where in Ms. Carlino's body this slide came from, can you?

A. Definitely came from the sling. I mean, this is part of the sling.

Q. Okay. And if we were to have a diagram, and you were to have to point out where this was in orientation to her body, you would not be able to do that, would you?

A. Well, it was in the area where the sling was placed, so it's suburethral, somewhere in that area. But, optimally, no, I could not. I can generally tell you the location but not --

Q. And same question that I've asked before, you can't tell us where in the specimen the

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slide came from, can you?

A. No. I mean, I can tell you where on the slide. If I have the slide, I will find the area.

Q. Now it's my understanding in your testimony you're using the stain to show the presence of myeloperoxidase, right?

A. Yes, it's one of the substances that can be stained. There are many other oxidative substances around, but we don't have stains for those.

Q. Is there any literature that you can point me to, that shows the use of myeloperoxidase stain to stain for extracellular myeloperoxidase?

Is that question clear? If not, I'll try to do better.

A. I don't understand your question.

Myeloperoxidase is stain, so it detects its presence. Intracellular or extracellular, you make your own assessment using your eyes.

Q. It's a nuclear stain, isn't it?

A. No. Myeloperoxidase is enzyme, which is produced inside the body and it spills

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out. So that's completely wrong.

Q. Can you point me to any literature that describes the use of myeloperoxidase stain to look for myeloperoxidase outside of the cell nucleus?

A. I don't understand your question. Is any literature pointing the difference, if you see staining inside the nucleus or outside the plasma, or outside the center plasma in the extracellular space; is that what you're asking?

Q. Yes.

A. I can't think, why would you do that?

Q. The question is: Is there any literature you can point me to?

A. It wouldn't be scientific question to do that.

Q. Is there any --

A. No. There is, no, because there is no scientific question to answer.

Q. Now, can you point to any literature that describes using myeloperoxidase stain in the manner that you're using it in SC-11 to show myeloperoxidase spread throughout the

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tissue?
A. My publication.
Q. Anything else? Has anybody else --
A. No.
Q. Are there any other publications you can refer us to that would describe it?
A. I don't think so. Not that I remember.
Q. Is there any tissue necrosis?
A. Pardon?
Q. Any tissue necrosis depicted in SC-11?
A. I don't think so. I mean, necrosis is -- large area of necrosis, no, I don't see it.
Q. What concentration of myeloperoxidase would it take to cause degradation of polypropylene?
A. Question is wrong.
First, it's not just myeloperoxidase which is causing it.
Second, nobody measured it. I don't think you can do it.
Q. You had not measured it?

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A. No, I didn't.
Q. And you're not aware of anybody else measuring it?
A. Why? My purpose was to detect degradation.
Q. So my question is, you're not aware of anyone else measuring it, are you?
A. No. And I wouldn't.
Q. Dr. Iakovlev, is it collectively -- I want to ask you a question about SC-12 through 18.
Are those slides that you prepared to discuss what you believe is degradation of the mesh in Ms. Carlino?
A. That's correct.
Q. And what is it that you're going to tell the jury about this slide?
A. This shows that polypropylene degrades while in the body and then becomes brittle, cracks.
Q. Anything else that you're going to tell the jury about those slides?
A. That's the main thing. I mean, it degrades, changes physical characteristics over

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time, becomes brittle.
Q. And are you going to tell the jury that this has a clinical impact on Ms. Carlino?
A. If it's brittle, if it changes physical characteristics, it becomes stiff, firmer. It's clearly brittle material.
Q. I'm sorry, I couldn't hear you.
A. It's clearly brittle material, it cracks.
Q. Okay. What does your contention that this is brittle material, what is the clinical impact that you're going to tell the jury it had on Ms. Carlino, if any?
A. Mainly, increase in stiffness.
Might be some significance to track bacteria, but in this case, I don't see evidence of bacterial infection. So mainly, it's increase in stiffness.
Q. And I just want to make sure I know everything that you're going to tell the jury about the degradation that you say that you identified in slides SC-12 through 18. For the clinical impact it would be that it would increase stiffness, nothing else?

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A. Well, there is also the process which occurs. I mean, when it degrades, I mean, there will be some chemicals released. We don't know exactly which chemical released.
So they are -- the tissue around it exposed to these chemicals. Again, that specific part is not studied as in details. We just know that it occurs or can predict.
Q. And in regard to Ms. Carlino's case, you have not detected any tissue necrosis, have you?
A. See, sometimes I can see some amorphous material around the mesh fibers. And I can see in that. I don't think it's specifically tissue necrosis, but it's some substance which is not alive. So there is some turnover around the mesh fibers.
And Klinge it showed that there is constant turnover around the fibers. So something is driving sort of constant replacement of the tissue. It's been shown in the studies.
What is driving it? Is it just inflammation or inflammation and some substances which are released? I mean, it may be different

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from the meshes.
We just know that polypropylene degrades, and there is some turnover. So some tissue becomes replaced, so it goes necrotic and becomes replaced, just around the fibers.
So these are the pieces of information what we know from published literature.
Q. Can you show me on any of the slides, any place where you're going to point to and say, "that is evidence of tissue necrosis in Ms. Carlino's case"?
A. No, I wouldn't be able to. It's more a replacement rather than necrosis. Kosterhaliften and Klinge show that there is replacement tissue around the fibers.
Q. Okay. There's nothing on the slides that you're going to point to and say, "that shows necrotic tissue"?
A. No.
Q. What is the clinical impact that you contend occurs because of the mesh being increased on stiffness?
A. Damages tissue.
Q. I can't hear you.

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A. Damages tissue.
Q. And what damage to the tissue is caused by the increased stiffness?
A. Well, if it's firmer than tissue, then it can damage tissue, because it's harder than tissue, stiffer and harder.
Also, if there is any sort of internal deformation forces slowly over years, it start to curl. So this would be the implications.
Q. And for Ms. Carlino's case, have you quantified in any way that increase in stiffness?
A. No, I couldn't. I just see that it's brittle, it's not as elastic or as flexible as non-degraded polypropylene.
Q. How is it that you quantify stiffness?
A. I don't. I just see that one material is more brittle than the other.
Q. And the way that you would quantify that would be through testing tensile strength, isn't it?
A. If you want to quantify it, yes, but I'm not doing quantification. I'm just doing

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qualitative analysis, more brittle or less brittle.
Q. I understand. And you have not tested Ms. Carlino's mesh in any way to see if there was a increase in tensile strength?
A. Tensile strength, no. Tensile strength and stiffness are a little bit different.
Q. You haven't done any quantitative testing of Ms. Carlino's mesh to show an increase in stiffness?
A. As I said, I answered. I did not quantify it, I only qualified it. And qualified it the way that the degrading material is more brittle, or brittle, and I don't see the brittleness in non-degraded part.
So the degraded layer changed physical characteristics, it became brittle.
Q. And it's your opinion that as a result of polypropylene degradation, the external layer of Ms. Carlino's mesh would be more stiff?
A. Yes, brittle. Brittle and stuff are similar terms.
Q. Did you measure -- and obviously we've taken your deposition before on this, and I know that you've referred to it as "bark", the

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external layer.
Did you measure the thickness of the bark for Ms. Carlino's mesh?
A. 4.5 microns median. Most frequent measurement was 4.5 microns.
Q. Okay. And that would be -- you're going to test my math here.
That would be 1/200th of a millimeter?
A. You lost me there. I'm not good at math.
Q. All right. In any event, your calculation is that the median thickness of the bark for Ms. Carlino was 4.5 microns?
A. Yes.
Q. Dr. Iakovlev, I want to ask you some questions now about the clinicopathological correlations that you made in this case.
And it's my understanding you have that set forth on pages 87 through 90?
A. Yes.
Q. I want to make sure that I understand the boundaries of your clinicopathological correlation.
You've told us before that you would

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never have examined Ms. Carlino, correct?
A. That's correct.
Q. This will be a little of a run-on question. But you never talked to her, never talked to her treating physicians, never read the depositions, and never had a doctor-patient relationship with her; is that correct?
A. That's correct.
Q. And same questions regarding her husband; you never have examined him?
A. No.
Q. You never talked to him?
A. No.
Q. Never reviewed any depositions related to him?
A. No.
Q. Now, in your clinicopathological correlation, you make -- strike that -- you have opinions regarding Ms. Carlino's dyspareunia; is that correct?
A. That's correct.
Q. Now, you're not a urologist, are you?
A. No.

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Q. Not a urogynecologist?
A. No.
Q. You don't implant mesh?
A. No.
Q. Don't explant mesh?
A. No.
Q. You don't counsel or treat patients with dyspareunia?
A. No.
Q. Don't counsel or treat patients with urinary symptoms?
A. No.
Q. Don't prescribe medication for pain, pelvic pain or dyspareunia?
A. That is correct.
Q. Now, in your clinicopathological correlation at the bottom of page 88, you have: "Removal of the mesh does not eliminate the pathological factors described above."
What does that mean?
A. Well, there is no way back. That's pretty much the basis of it. Because once you place a mesh, then the damage of the mesh placement cannot be eliminated.

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First, there is damage from the mesh and then there is damage from the excision surgery, and then that empty sort of space after excision needs to heal so it gets replaced by scar tissue.
Essentially, it will never be the same. That is the essence of it.
Q. And that opinion that you have, is inconsistent with Dr. Conner's opinion, isn't it?
A. Possible, I mean, everybody is entitled to an opinion.
Q. Okay. And we looked earlier at Dr. Conner's note, which we marked as Exhibit 5, where Dr. Conner stated that this was -- that the removal of the mesh resulted in complete resolution of her pelvic pain and dyspareunia, but worsening in her stress incontinence. That would be inconsistent with your opinion, wouldn't it?
A. Well, that's resolution of symptoms for that period of time. It doesn't say that there is resolution of pathological changes. We're talking about different things.
I'm talking about pathology. Each tissue changes. He's talking about specific timeframe within what he didn't elicit the

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symptoms. I mean, we don't know what was after that, and if the symptoms were subclinical or were not reported. I don't know.
Q. And so what you're talking about are pathological changes, not symptomatic changes.
A. Pathological changes, which place tissue at risk for symptomatic manifestations.
Q. Okay. And would you defer to a urogynecologist on whether those pathological changes were or were not causing pelvic pain and dyspareunia for Ms. Carlino?
A. Yes and no.
As long as the patient has good report with the clinician. They may or may not report it. They may or may not feel it's significant enough, I mean, so there are many other factors why patients report and don't report.
There's also the time factor, if it doesn't happen now, it may happen two years later.
Q. And you would agree that Dr. Conner's opinion was that mesh removal and revision of the sling had resulted in complete resolution of pelvic pain and dyspareunia as of April 26, 2011?

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A. At that time his opinion was like you stated.
Q. Dr. Iakovlev, in your paper that you published with Dr. Blaivis, you made an estimate of dyspareunia pain from transvaginal slings, didn't you?
A. So to remind you that we're going into general again. The paper -- I'll still answer.
The paper was estimating what could be minimum number for specific complications. Then it was giving a range, and then it was discussing why these numbers may or may not be reliable.
So there are many numbers there, and some of them need to be taken with a specific angle because of the factors that I had described.
Q. And I don't remember the exact word, but it was something like 3 percent, wasn't it, for dyspareunia pain?
A. If it was minimum, minimum possible, out of what was published, could be. I mean, the minimum numbers are always low. The true number can be several fold higher.
So the range, I think was much higher,

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there was a large spread. And then we were discussing why these numbers can be artificially low, unreliable and so forth.
So don't pluck just one number and say, that is the truth, no. That paper was a discussion it was showing what was published, equality of publications and so forth.
So I think in one table it was minimum estimated, so it cannot drop lower than that, but it can be ten times higher.
Q. And that was something like 3 percent, right?
A. Not lower than that, this is the bottom. This is the smallest number possible. But the true number maybe 35 to 40 percent.
Q. All right. The number that is in your paper in that table is something like 3 percent, isn't it?
A. The minimum possible number.
Q. That's fine. The qualification, I'm sorry, I'll do it again.
The minimum number that's in that table, it's 3 percent; isn't it?
A. Reported. The minimum reported

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number is 3.5 percent. The true number, we estimate is many fold higher.
Q. Now Ms. Carlino, what other risk factors did she have for dyspareunia?
A. So the most common and easily treatable factor is vaginal atrophy, I mean depending on age.
Q. I'll represent to you that Ms. Carlino was postmenopausal, and in fact correlated with vaginal atrophy?
A. Yes, it would be. So the usual course of action, which I see in the histories, is to try to treat the atrophy most commonly with local estrogen cream.
Q. Do you know whether Ms. Carlino was or was not treated with local estrogen cream?
A. I don't remember now. It's so easily done. Even, there was obvious mesh involvement, at least that part can be treated.
Q. Again, my question is: Do you know whether Ms. Carlino was treated with vaginal estrogen?
A. I do not.
Q. Okay. Now is vaginal hysterectomy

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also a risk factor for dyspareunia?
A. Not if it's done correctly. Not if there's no complications. Not that I'm aware of.
Again, I think we're going into general and then not my field. I mean, it's little bit beyond my expertise.
Q. If this is beyond your field of expertise, just tell me that.
Is the calculation of the relative risk factors of dyspareunia beyond your expertise?
A. What is most important when I go through the history that at one point of time all investigations culminate in mesh excision, and I receive the specimen.
Mesh is excised for symptoms. When examined, the disease is in mesh in the specimen. That is the main, sort of fundamental factors which are influencing my opinions.
Q. Okay. Let's talk about other risk factors that Ms. Carlino had.
Vaginal atrophy, "yes" or "no"?
A. Possible. I mean, they all have. But again, she ended up with excised mesh.

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Q. Hysterectomy; is that a risk factor?
A. I don't know. It's beyond my expertise.
Q. Do you know whether there are published rates for the dyspareunia rate associated with vaginal hysterectomy?
A. I don't know. It's beyond my expertise.
Q. Do you know whether Ms. Carlino had pelvic floor muscle dysfunction?
A. Again, it's beyond my expertise.
I leave that into clinical workup. When I step in, when the decision is made to excise the mesh and there is a pathology specimen; that's where my involvement becomes important. Because I can answer what is wrong with that specimen.
MR. COMBS: Let's mark that as Exhibit 11.
EXHIBIT NO. 11: Diagram of the Female Genitalia.
BY MR. COMBS:
Q. Dr. Iakovlev, would you be able to take a magic marker and show us where on this

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diagram Ms. Carlino's dyspareunia was?
Do you know at what point in her vagina Ms. Carlino reports pain?
A. You're asking the wrong person. I'm not a clinical specialist. I didn't examine her, I would not be able to answer it.
Q. That's fine. So you would not be able to put on this diagram where Ms. Carlino has made reports of pain?
A. Where she felt pain?
Q. Yes, sir.
A. No, I would not. I didn't examine her.
Q. Let me ask you a couple of questions about your clinicopathological correlation regarding urinary symptoms.
A. Uhm-hmm.
Q. Do you know whether Ms. Carlino was continent after the sling was placed?
A. Okay. So she had stress incontinence before the mesh was placed. And then after the mesh placement in 2010, there is stress incontinence, and frequent UTIs, and symptoms of urgency and dysuria.
So clinical record described little

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more, in addition to stress incontinence, they described urgency and UTIs. So she was not fully continent in 2010.
Q. So let me ask you a more specific question. Was she continent between the time when she had the mesh implantation in 2005 and the first revision in 2007?
A. It's possible that she was. I mean, I don't remember now.
Q. As we sit here today, you don't know whether she was continent in that period?
A. I don't remember. And for what period she was continent, and if she was continent at all for any period. There could have been some improvement, I don't remember.
Q. As a pathologist, you do not diagnose SUI, do you?
A. No.
Q. You do not diagnose urge incontinency, do you?
A. No.
Q. Dr. Iakovlev, as a pathologist, you would be able to detect whether Ms. Carlino had cancerous cells; wouldn't you?

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A. If it's present in this specimen, yes.
Q. And you did not make any finding that Ms. Carlino had cells that were cancerous, did you?
A. In the specimen I examined?
Q. Yes, sir.
A. That's correct. I didn't find any neoplasia.
Q. And you did not find any loose particles in Ms. Carlino's specimen, did you?
A. What do you mean "loose particles"?
Q. You did not find any loose particles of mesh that had come detached from the mesh in her specimen, did you?
A. Sometimes I see some particles, sometimes not. It's usually not a large volume. I don't remember that. Again, I don't make special note of it.
Q. Okay. In Ms. Carlino's case, you don't have documented anywhere that you saw those particles, do you?
A. As I said, I don't pay specific attention. Sometimes I see more than I would

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visually expect and take picture. But it's not that common.

Q. In this case you would not be providing any opinion that Ms. Carlino had particle loss from loose particles from the mesh; will you?

A. At least not in the volume that it would draw my attention.

Again, I'm using light microscopy. What I can see by light microscopy that's as far as I can go.

Q. And you didn't make any finding of that in this case?

A. No, nothing that beyond what I could see normal in the specimens or usually in the specimens.

Q. All right. And again, there are not any slides that you're going to point to at this trial and say, hey, there's a loose particle?

A. No.

Q. Was Ms. Carlino's mesh laser cut or mechanically cut?

A. I don't know. Doesn't make difference to me.

Q. For your purposes that's not

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important, is it?

A. No.

Q. The pathological findings from mechanically cut mesh and laser cut mesh would be the same, wouldn't it?

A. They are somewhat different, because heat-treated central portions of some slings don't curl as much; and sometimes I can see the ends, which are melted.

Q. Do you know whether the central portion of the Ethicon mesh has been treated? Look, again --

A. Some companies switch it halfway.

Q. -- I'm not trying to trip you up or anything. Boston Scientific has a central portion that's heat-treated.

A. Some edges are cut by laser cut, so they're melted. But the mesh itself is still flexible, it's not heat-treated.

And then some companies went further. The edges were melted and the central portion was somewhat ironed.

TVT mesh, Ethicon, I don't think the central portion is heat-treated, but the edges may

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have different type of cutting at certain time period.

Q. And you do not plan on providing testimony at this trial that there are any pathological findings that you would attribute to the way in which Ms. Carlino's mesh was cut?

A. No. I can say that the twisted part was not heat-treated, because heat-treated usually doesn't twist that much.

Q. All right. Any other pathological findings that you're going to talk to this jury about that would relate to the way in which Ms. Carlino's mesh was cut?

MR. ZIMMERMAN: Objection. Overbroad.

He'll testify to what questions counsel asks in the trial, which are consistent with and in the scope of his expert report.

THE WITNESS: We talked about many things. I may not remember everything it could generate. It feels like we covered most of it, maybe some details were missed.

MR. COMBS: Dr. Iakovlev, that's either all my questions or really, really close. Let's take a break for two minutes.

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-- RECESS AT 2:36 --

-- UPON RESUMING AT 2:47 --

BY MR. COMBS:

Q. Dr. Iakovlev, just a couple of more questions for you. First is, you told us the median bark measurement was 4.5 microns. How many measurements did you take in this case?

A. I take at least four measurements. Sometimes I can make only four; it depends on the specimen. Sometimes it goes up to six, it depends.

Q. Okay. So somewhere between 4 and 6 measurements in this case?

A. Usually.

Q. Did you keep a record of which fibers you were measuring?

A. No.

Q. All right. In other depositions I've seen you discuss the issue of nanocavities for trapping stain.

And I just want to ask you: Did you detect any nanocavities in the Carlino mesh?

A. I think we covered this in the earlier deposition. I detect them by seeing purple color, that's the detection mechanism.

Q. Can you point to any nanocavities in the pictures of the slides in your --

A. It's purple. That's why it stains, because it's trapped in the cavities.

Q. None of your pictures are acute enough resolution to show the nanocavities.

A. Not for this one. We did transmission electron microscopy. I did it once, and I don't think I will do it again.

Q. And then finally, I think I asked you this, but I just want to make sure that I didn't forget.

You have not looked at the defense expert reports in this case, have you?

A. No.

MR. COMBS: All right.

Thank you, Dr. Iakovlev. That's all the questions I have for you at this time.

-- Whereupon the deposition adjourned at 2:49 p.m.

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 18th day of November, 2015.

_____

PER: JUDITH CAPUTO, RPR, CSR, CRR

CERTIFICATE OF REPORTER

CANADA)

PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

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Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking Oaths in the Province of Ontario

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NAME OF CASE: SHARON CARLINO, ET AL. V. ETHICON, ET AL.
DATE OF DEPOSITION: NOVEMBER 5, 2015
NAME OF WITNESS: VLADIMIR IAKOVLEV, M.D.

PAGE	LINE	CORRECTION	REASON

_____
VLADIMIR IAKOVLEV, M.D.

PROVINCE OF ONTARIO)
TORONTO REGION)

I, the undersigned, declare under penalty of perjury that I have read the foregoing transcript, and I have made any corrections, additions or deletions that I was desirous of making;

That the foregoing is a true and correct transcript of my testimony contained therein.

_____
VLADIMIR IAKOVLEV, M.D.

Subscribed and sworn to before me this ____
Day of _____, 2015 at
_____, _____.
(City) (Province)

_____
(Notary Public)
My Commission Expires: _____